EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

DePuy Mitek's Statement of Undisputed Material Facts in Support of its Motion for Summary Judgment of Infringement and No Inequitable Conduct

I. Statement of Undisputed Material Facts in Support of DePuy Mitek's Summary Judgment of Infringement Memorandum

Mitek Fact #1

Claim 1 of U.S. Patent No. 5,314,446 Patent ("446 Patent") is:

> A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and
>
> a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
>
> b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
>
> c) optionally a core (Ex. 1 at 8:63-9:9).

Mitek Fact #2

Claim 2 of Mitek's 446 Patent is "[t]he surgical suture of claim 1 wherein the suture is attached to a needle (*id.* at 9:10-11).

Mitek Fact #3

Claim 8 of Mitek's 446 Patent is "[t]he surgical suture of claim 1 wherein the second set of yarns is PET" (*id.* at 10:7-8).

Mitek Fact #4

Claim 9 of Mitek's 446 Patent is "[t]he surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent" (*id.* at 10:9-11).

Mitek Fact #5

Claim 12 of Mitek's 446 Patent is "[t]he surgical suture of claim 8 wherein the suture is attached to a needle" (*id.* at 10:18-19).

Mitek Fact #6

The 446 patent states that "it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid" (*id.* at 2:58-62).

Mitek Fact #7

The 446 patent states that "[s]urprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security" (*id.* at 2:49-66).

Mitek Fact #8

TigerWire is made by Pearsalls and sold by Arthrex (Ex. 2 at ARM18533).

Mitek Fact #9

TigerWire's yarns are identical to FiberWire with the exception that one PET yarn is replaced by one nylon yarn (Ex. 3).

Mitek Fact #10

TigerWire is braided in the same way as FiberWire (Ex. 4 at 31:24–32:2).

Mitek Fact #11

FiberWire and TigerWire are surgical sutures (Ex. 5).

Mitek Fact #12

FiberWire sutures contain a sheath or cover formed by braiding yarns of polyethylene (PE) and yarns of polyethylene terephthalate ("PET") (Ex. 4 at 43:15-19; Ex. 5).

Mitek Fact #13

Dr. Mukherjee testified that:

Q. Okay. And is the FiberWire heterogeneous braid composed of a first and second set of continuous and discrete yarns?
A. Yes.
Q. Okay. And is the FiberWire heterogeneous sheath braid composed of discrete yarns in a sterilized braided construction?
A. Yes (Ex. 6 at 362:1-8).

Mitek Fact #14

Dr. Mukherjee is Arthrex's expert who submitted an expert report opining that FiberWire does not infringe the 446 Patent.

Mitek Fact #15

The polyethylene terephthalate yarns in FiberWire and TigerWire are continuous and discrete (*id*. at 362:1-4).

Mitek Fact #16

Mr. Dreyfuss testified that:

Q. What is -- How do you characterize that strand of polyethylene when Pearsalls receives it?

A. It is a various -- various individual filaments make up the yarn that's received. And the yarn may be several filaments to many (Ex. 4 at 50:21-51:1) (objection omitted).

Mitek Fact #17

Mr. Dreyfuss testified that:

Q. Same way? So the PET used in Arthrex's FiberWire sutures is in the form of yarn, and that PET yarn is made up of several twisted monofilaments of PET?

A. Correct (*id*. at 64:14-17).

Mitek Fact #18

Dr. Mukherjee testified that:

Q. And does the FiberWire heterogeneous braided sheath have a braided construction where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set?

A. There is intertwining contact, yes (Ex. 6 at 362:9-14).

Mitek Fact #19

There are no bioabsorbable materials in FiberWire or TigerWire (Ex. 5).

Mitek Fact #20

FiberWire and TigerWire have a coating and both FiberWire and TigerWire have a heterogeneous braid of dissimilar non-bioabsorbable yarns of PE and PET, materials, wherein the PE yarns are in direct intertwining contact with the PET yarns, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid (Ex. 7 at ¶36).

Mitek Fact #21

FiberWire is made from ultra high molecular weight PE ("UHMW PE"), which is a type of PE (Ex. 8 at ¶¶149-157).

Mitek Fact #22

Arthrex documents refer to UHMW PE as simply PE (Ex. 5; Ex. 9 at ARM002188-89; Ex. 10).

Mitek Fact #23

Different FiberWire sizes are braided in the same manner (Ex. 4 at 38:20-24).

Mitek Fact #24

The FiberWire size 4-0 suture has the same sheath configuration as the other size FiberWire sutures (*id*. at 104:17-105:9).

Mitek Fact #25

FiberWire size 4-0 does not have a core (*id*. at 55:21-23).

Mitek Fact #26

Arthrex's FiberWire and TigerWire suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF,AR-1934BF, AR-1934BF-2, AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF, AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (Ex. 2).

Mitek Fact #27

Mr. Grafton testified:

Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes (Ex. 11 at 51:15-17).

Mitek Fact #28

Mr. Grafton testified:

Q. Okay. And you said the strength was excellent, I believe, of the initial prototype, but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product (*id*. at 52:5-12).

Mitek Fact #29

Mr. Grafton testified:

Q. Ultra-high molecular weight polyethylene, is that a lubricious material?
A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes (*id*. at 52:24-53:5).

Mitek Fact #30

Mr. Grafton testified:

Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?
A. I've lost count, it's been so many times, but the answer again is yes (*id*. at 53:20-54:5) (objection omitted).

Mitek Fact #31

Mr. Grafton testified:

Q. And the prototype of PET braided with ultra-high molecular weight polyethylene had good knot security?
A. Yes (*id*. at 54:24-55:1).

Mitek Fact #32

FiberWire does have a coating that acts as a lubricant (Ex. 5).

Mitek Fact #33

Dr. Brookstein stated that FiberWire's coating does not materially affect the basic and novel characteristics of the invention as defined by Mitek (Ex. 7 at ¶36).

Mitek Fact #34

Regardless of the coating, FiberWire still has a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid (*id*. at ¶36).

Mitek Fact #35

FiberWire's coating is non-bioabsorbable (Ex. 5).

Mitek Fact #36

FiberWire's coating does not materially affect the non-bioabsorbability of FiberWire's yarns (Ex. 7 at ¶36).

Mitek Fact #37

FiberWire coating does not materially affect FiberWire from having PE braided in direct intertwining contact with PET (*id*.).

Mitek Fact #38

FiberWire's coating does not materially affect FiberWire's PE and PET yarns from contributing to the overall properties of the heterogeneous braid (*id*.).

Mitek Fact # 39

Mr. Dreyfuss testified:
Q. What is the purpose of the nylon marking strand in Arthrex's TigerWire product?
A. Identification. Visual identification (Ex. 12 at 74:21-23).

Mitek Fact # 40

Dr. Brookstein stated that TigerWire's single nylon strand does not materially affect the basic and novel characteristics as defined by Mitek (Ex. 7 at ¶45).

Mitek Fact # 41

Nylon makes up only about 3.4% of the TigerWire suture (Ex. 3).

Mitek Fact # 42

The inclusion of a nylon yarn instead of one yarn of PET does not materially affect the basic and novel characteristics of the invention because the braid is still a heterogeneous braid of non-bioabsorbable yarns of the type claimed (Ex. 7 at ¶45).

Mitek Fact #43

The inclusion of a nylon yarn instead of one yarn of PET does not materially affect the basic and novel characteristics of the invention because at least one yarn of PE is in direct intertwining contact with a PET yarn (*id*.).

Mitek Fact #44

The inclusion of a nylon yarn instead of one yarn of PET does not materially affect the basic and novel characteristics of the invention because the nylon does not materially affect the yarns from contributing to the properties of the overall braided suture (*id*.).

Mitek Fact #45

Mr. Dreyfuss testified:

Q. Other than the visual distinction that you can see with the introduction of a nylon marking strand, does the nylon marking strand in TigerWire affect any other characteristic of the braided suture?
A. Yes.
Q. What is -- what?
A. Minute differences in its feel and strength, characteristics (Ex. 12 at 75:7-14).

Mitek Fact #46

Dr. Mukherjee testified that:

Q. Okay. And the next part says, "Each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group of PET, nylon and aramid." Do you see that?
A. Yes.
Q. Does FiberWire meet that criteria?
A. It has the PET in it.
Q. So, it meets that criteria?
A. Uh-huh (Ex. 6 at 363:7-16).

Mitek Fact #47

Arthrex's FiberWire sutures have a core except for 4-0 FiberWire (Ex. 3).

Mitek Fact #48

Arthrex's FiberWire needle products have either FiberWire suture attached to a needle (Ex. 2).

Mitek Fact #49

Each FiberWire suture product has PET as a second set of yarns (Ex. 3).

Mitek Fact #50

Every FiberWire and TigerWire construction has a ratio of the cross-sectional area of ultra high molecular weight PE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent (Ex. 7 at ¶49; Ex. 3).

Mitek Fact #51

Arthrex, Inc. sells FiberWire and TigerWire in the United States (Ex. 13).

Mitek Fact #52

Arthrex's FiberWire and TigerWire needle products includes all Arthrex's products that are sold with a needle attached to a FiberWire or TigerWire suture including at least the following Arthrex catalog product codes AR-7200, AR-7202, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7211, AR-7219, AR-7220, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1324BNF, AR-1920BNP, AR-1934BNF, AR-1920BN, AR-1920BNF, AR-1925BNF, AR-1925BNP, AR-1927BNF, AR-1928SNF, and AR-1928SNF-2 (Ex. 2).

II. Statement of Undisputed Material Facts in Support of DePuy Mitek's Summary Judgment of No Inequitable Conduct Memorandum

Mitek Fact #53

The application that matured into U.S. Patent No. 5,134,446 (the 511 application) was filed on February 19, 1992 (Ex. 1).

Mitek Fact #54

Dr. Mark Steckel is named as a co-inventor of the 511 application (Ex. 1).

Mitek Fact #55

The 511 application as originally filed had 24 claims (*id*. at DMI 000033-36).

Mitek Fact #56

Originally filed claims 1-20 ("braid claims") of the 511 application are drawn to a heterogeneous braid (*id*. at DMI000033-35 and 187).

Mitek Fact #57

Originally filed claims 21-24 ("suture claims") of the 511 application are drawn to a surgical suture (*id*. at DMI000035 and 187).

Mitek Fact #58

Messrs. Matthew Goodwin and Hal Woodrow are two in-house attorneys from Johnson & Johnson (Ex. 14 at 7:9-21, 8:4-10; Ex. 15 at 6:25-7:4).

Mitek Fact #59

Messrs. Matthew Goodwin and Hal Woodrow prosecuted the 511 application (Ex. at 16 at DMI000014, 15, 64, 197, 250, and 261).

Mitek Fact #60

On February 19, 1992, the day the 511 application was filed, Mr. Goodwin submitted an Information Disclosure Statement for the 511 application (*id*. at DMI000010 and 63-64).

Mitek Fact #61

Mr. Goodwin disclosed eleven references including U.K. Patent Application GB 2 218 321A ("Burgess") in the information disclosure statement dated February 19, 1992 (*id.* at DMI000063-64 and 185).

Mitek Fact #62

During the prosecution of the 511 application, the first office action issued on July 8, 1992 (*id*. at DMI000186).

Mitek Fact #63

In the first office action, the U.S. Patent & Trademark Office ("Patent Office") issued a restriction (*id.* at DMI000187-188).

Mitek Fact #64

The first office action states that claims 1-20 were useful as a fishing line (*id*. at DMI000187).

Mitek Fact #65

The first office action states that the invention of claims 1-20 are patentably distinct from the invention of claims 21-24 (*id*. at DMI000187-88).

Mitek Fact #66

The first office action states that the inventions of the braid and suture claims "have acquired a separate status in the art because of their recognized divergent subject matter" (*id.* at DMI000188).

Mitek Fact #67

Applicants elected to prosecute the "suture" claims (*id.*).

Mitek Fact #68

The Examiner stated that there is nothing in the record to show the braid claims and suture claims are obvious variants (Ex. 16 at DMI000187).

Mitek Fact #69

In the first office action, the Patent Office rejected the suture claims as obvious or not patentably distinct over U.K. Patent Application 2,218,312A, (Burgess) (*id.* at DMI000189).

Mitek Fact #70

U.K. Patent Application 2,218,312A, (Burgess) discloses a fishing line (*id*. at DMI000122-125).

Mitek Fact #71

In the first office action response, Mr. Goodwin confirmed the prior election to prosecute the sutures claims without traverse (*id*.).

Mitek Fact #72

In the first office action response, Mr. Goodwin traversed the Examiner's rejection of the suture claims over the Burgess fishing line reference (*id.*).

Mitek Fact #73

In the first office action response, Mr. Goodwin argued that Burgess was nonanalagous art (*id*. at DMI 000194-197).

Mitek Fact #74

In the first office action response, Mr. Goodwin argued that persons wanting to make a suture would not look to the fishing line art as instructive (*id*.).

Mitek Fact #75

In the first office action response, Mr. Goodwin argued that some of the property considerations for fishing lines, such as disclosed in Burgess, are different from some of the property considerations for surgical sutures (*id.*).

Mitek Fact #76

In the first office action response, Mr. Goodwin pointed out that an important characteristic of sutures –which holds wounds together– is knot strength (*id*. at DMI 000195).

Mitek Fact #77

Burgess does not mention knot strength (*id*. at DMI000122-125).

Mitek Fact #78

In the first office action response, Mr. Goodwin explained that sutures and fishing line have different requirements because a surgeon ties sutures into conventional square knots at a very fast pace for patient safety (*id*. at DMI000196).

Mitek Fact #79

In the first office action response, Mr. Goodwin explained that sutures and fishing line have different requirements because surgeons generally form a pre-knot with a suture and then slide it down the suture until the knot is adjacent to the body tissue desired to be stitched (*id*.).

Mitek Fact #80

In the first office action response, Mr. Goodwin explained that sutures and fishing line have different requirements because after a suture knot is placed, surgeons make additional throws that can be added for knot security (*id*.).

Mitek Fact #81

In the first office action response, Mr. Goodwin noted that the Burgess fishing line had some filaments composed of high tensile polythene thread which, although having some good strength properties, has poor knot strength properties (*id.* at DMI000195-196).

Mitek Fact #82

In the first office action response, Mr. Goodwin explained the dissimilarities in property requirements for sutures versus fishing lines (*id*.).

Mitek Fact #83

In the first office action response, Mr. Goodwin stated "[i]n view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a suture, then he would inevitably design an unacceptable suture" (*id.* at DMI000196-197).

Mitek Fact #84

After receiving the first office action response, the Examiner issued a second office action ("the second office action") during the prosecution of the 511 application (*id*. at DMI000201-205).

Mitek Fact #85

The second office action states that the rejection over Burgess was moot (*id*. at DMI000204).

Mitek Fact #86

After the second office action, there was no further discussion of Burgess during the prosecution of the 511 application (*id.*).

Mitek Fact #87

In the second office action, the Examiner rejected the suture claims over two different patents including U.S. Patent No. 5,147,400 (*id*. at DMI000202-203; 215-228).

Mitek Fact #88

The second office action states that Kaplan disclosed a core and a braided sheath component made from "individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorable" (*id.* at DMI000203).

Mitek Fact #89

Mr. Goodwin submitted a response to the second office action stating that the claimed inventions were distinguishable from Kaplan because Kaplan failed to disclose the claimed braid of direct intertwining contact (*id*. at DMI000239-244).

Mitek Fact #90

The Patent Office issued a third office action on March 18, 1993 during the prosecution of the 511 application ("third office action") (*id*. at DMI000246).

Mitek Fact #91

In the third office action, the Patent Office rejected the suture claims based at least in part on Kaplan (*id*. at DMI000247).

Mitek Fact #92

The third office action states that the Applicant's arguments in response to the second office action "are deemed moot in view of the new grounds of rejection" (*id*. at DMI000248).

Mitek Fact #93

The third office action states that Kaplan disclosed a braided sheath component that may be fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being nonbioabsorbable (*id.* at DMI000241-248).

Mitek Fact #94

On August 3, 1993, Mr. Woodrow submitted a response to the third office action ("third office action response") (*id*. at DMI000258).

Mitek Fact #95

In the third office action response, applicants amended the claims to exclude biomaterials as the first and second fiber-forming materials (*id*. at DMI000259).

Mitek Fact #96

In the third office action response, applicants argued that the claims were patentable over Kaplan (*id.* at DMI000259-261).

Mitek Fact #97

In the third office action response, Mr. Woodrow explained, *inter alia*, that Kaplan did not anticipate or render obvious the amended claimed invention because Kaplan disclosed sheath yarn components that are "bioabsorbable or semi-bioabsorbable" (*id.* at DMI000259), and the amended claims recited nonbioabsorbable yarns (*id.*).

Mitek Fact #98

After the third office action response was submitted, the Patent Office issued a Notice of Allowance for the 511 application (*id.* at DMI000266).

Mitek Fact #99

Arthrex does not allege that any material information was withheld with respect to Kaplan (Ex. 17 at ¶¶18-21; Ex. 19).

Mitek Fact #100

Arthrex alleges that inequitable conduct was committed with respect to Kaplan because the 511 patent applicants and their attorneys mischaracterized and misrepresented Kaplan (Ex. 17 at ¶19).

Mitek Fact #101

Arthrex's allegations of inequitable conduct regarding Burgess are based on Mr. John Witherspoon's opinions (Ex. 20 at ¶¶58-63; Ex. 21 at ¶¶ 5-9).

Mitek Fact #102

Mr. Witherspoon opined that the following three statements in the response to the rejection over Burgess were affirmative misrepresentations:

- In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction;
- The property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security; and
- Even if [a medical designer] did use the teachings of the fishing line art to modify a suture then he would inevitably design an unacceptable suture (Ex. 21. at ¶7).

Mitek Fact #103

Mr. Witherspoon states that the three statements of fact 105 are material misrepresentations because Dr. Steckel allegedly testified that he "believed that a braided structure of Dyneema [a tradename for a type of polyethylene] and PET (a polyester) could have good knot characteristics" (*id.* at ¶¶6, 8 *citing* Dr. Steckel at 188:13-192:9).

Mitek Fact #104

Kaplan was discussed in two office actions and two responses during the prosecution of the 511 application (Ex. 16 at DMI000201-205; 235-242; 246-249; 258-263).

Mitek Fact #105

Kaplan was not withheld during the prosecution of the 511 application (*id.*).

Mitek Fact #106

The Patent Examiner considered Kaplan during the prosecution of the 511 application (*id.*).

Mitek Fact #107

Arthrex alleges that the 511 patent applicants and their attorneys falsely represented that Kaplan's sheath yarn component "always contains at least in part, a bio-absorbable portion and that Kaplan teaches away from a combination of non-bioabsorbable yarns" (*id.*).

Mitek Fact #108

Mr. Woodrow testified that:

Q. What was Ethicon's belief as to what Kaplan taught regarding the materials on the sheath of Kaplan?

A. That the sheath yarn is a biocompatible -- the sheath yarn is biocompatible and it is bioabsorbable or semibioabsorbable (Ex. 15 at 157:8-13).

Mitek Fact #109

Neither Dr. Gitis nor Dr. Mukherjee offered any opinions regarding Kaplan's teachings.

Mitek Fact #110

Mr. Witherspoon did not opine on any misconduct regarding Kaplan (Ex. 20 and 21).

Mitek Fact #111

Arthrex failed to plead any evidence of intent with respect to Kaplan in its answers (Ex. 17; Ex. 18).

Mitek Fact #112

Arthrex did not to identify any evidence of intent to deceive with respect to Kaplan in response to Mitek's interrogatories (Ex. 19).

Mitek Fact #113

Arthrex did not supplement its response to Mitek's interrogatory no. 6 after Arthrex deposed the prosecuting attorneys, Mr. Goodwin and Mr. Woodrow, and co-inventor Dr. Steckel.

Mitek Fact #114

Arthrex has no evidence that Mr. Woodrow thought Kaplan disclosed something different than what Mr. Woodrow explained to the Patent Office (Exs. 17, 18 and 19).

Mitek Fact #115

Dr. Steckel's testimony cited by Mr. Witherspoon in his rebuttal report was about his work developing *sutures* and what would make "an acceptable *suture*," not *fishing lines* (Ex. 21 at ¶6, *citing* Dr. Steckel at 188:13-192:9; Ex. 22 at 138:21-139:21).

Mitek Fact #116

There is no evidence that Dr. Steckel was familiar with fishing line properties.

Mitek Fact #117

There is no evidence that Dr. Steckel considered designing sutures from fishing lines.

Mitek Fact #118

There is no evidence that Dr. Steckel disagreed with Mr. Goodwin's argument that Burgess was nonanalogous art.

Mitek Fact #119

Mr. Witherspoon states in his March 3, 2006 report that: "If the term "PE" in the asserted claims of the '446 patent is construed by the court to include UHMWPE, then I would expect to testify that Dr. Steckel, and Mr. Hunter, and/or Mr. Goodwin may have violated their duty to disclose material information to the PTO, as required by Rule 56" (Ex. 20 at ¶58).

Mitek Fact #120

At his deposition, Mr. Witherspoon testified that:

Q. In paragraph 58 of your first report, you begin a discussion that proceeds for several paragraphs about whether Dr. Steckel, Mr. Hunter and/or Mr. Goodwin may have violated their duty to disclose material information to the Patent Office.
And I note that in that first sentence in paragraph 58, you say that "you expect to testify that these gentlemen may have violated their duty to disclose material information to the PTO." And I note the language may have violated. Do you intend to testify that they did violate their duty to disclose material, or that they may have violated their duty to disclose material information?
A. Well, I don't know quite how to answer

that, other than that it depends upon how the evidence at trial comes to -- comes in. And I say that because there's some additional information that I think needs to be found, for which I don't have access now, that would bear on whether there was a violation or not. And that turns on answers to the question of who knew what when. At this point in time, there's some circumstantial evidence that suggests that Mr. Steckel was aware of what the patent examiner had been told, but I can't point to a particular document or a piece of testimony that clearly establishes that. That's the reason for the use of the word may. In other words, there's a lot of information that indicates to me that there may have been a violation here, and this isn't just pulled out of thin air. But at this point in time, I could not specifically say what Dr. Steckel knew when, or what Mr. Goodwin knew when, or Mr. Hunter knew when. But there's evidence from which one could infer that they knew.

Q. And without evidence, without knowledge of what they knew, you cannot conclude that any of those gentlemen violated their duty of disclosure?

THE WITNESS: Could you read that back, please?

Q. And without knowledge of what those gentlemen knew, and when they knew it, you cannot conclude that any of them violated their duty of disclosure?

THE WITNESS: Well, no, I stand by the statement that I've made here, that they may have violated their duty. And I have referred to the deposition testimony of Dr. Steckel and Mr. Goodwin. But I would be -- I would not be inclined, at this point, to say that they, in fact, did violate it, knowing only what I know now (Ex. 22. at 184:7-186:18) (objections omitted).

Mitek Fact #121

Arthrex did not plead any evidence of intent to deceive with respect to Burgess (Ex. 17 at ¶¶18-21).

Mitek Fact #122

Arthrex did not identify any evidence of intent to deceive regarding Burgess in response to Mitek's interrogatory no. 6 (Ex. 19).

Mitek Fact #123

After Arthrex deposed Mr. Goodwin, Mr. Woodrow, and Dr. Steckel, Arthrex did not supplement its response to Mitek's interrogatory no. 6. interrogatory responses and identify any evidence of intent to deceive.

Mitek Fact #124

Dr. Steckel testified that:

A. Well, the patent describes generic classes of polymers, and the high strength aspect of it has more to do with how those polymers were processed. So, any of those polymers that are listed, you know, could be processed in a high strength form or a medium-strength form or a low-strength form.
Q. When you're saying, "these," which one are you talking about?
A. I'm referring to the polymers listed in the claims.
Q. All of them?
A. All of those can be processed to get a range of low, medium, or relatively high strength (Ex. 23 at 106:12-24).

Mitek Fact #125

U.S. Patent No. 5,314,446 discloses a suture having PE braided with PET in direct intertwining contact (Ex. 1 at 3:40-48; 4:30-40).

Mitek Fact #126

Dr. Steckel conceived of the idea of a suture having a braided sheath of ultra-high molecular weight PE and PET in direct intertwining contact before 1992.

Mitek Fact #127

Mr. Witherspoon testified at his deposition that:

Q. Do you plan to testify that material information was withheld from the examiner?

A. Well, you know, obviously, I don't know what questions I'll be asked. But if asked, I would so testify.
Q. And what material information would you testify was withheld from the examiner?
THE WITNESS: That Dr. Steckel and – at least Dr. Steckel, and perhaps Mr. Hunter as well, believed back in 1988 or '89 that a braid made of Spectra, an ultra high molecular weight polyethylene and polyethylene terephthalate, PET, could provide a successful suture, could provide a braid which could be converted into a successful suture.
Q. And it's your opinion that that was a material bit of information for the examiner?
A. Yes, because contrary information was being told to the examiner. Absent the contrary information, then I would not consider this information to be material. But it's material because it is inconsistent with what had been told to the examiner (Ex. 22 at 138:21-139:21) (objections omitted).

Respectfully submitted,

Dated: August 11, 2006

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EXHIBIT 1

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] Inventors: **Alastair W. Hunter**, Bridgewater; **Arthur Taylor, Jr.**, Plainfield, both of N.J.; **Mark Steckel**, Maineville, Ohio

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] **Int. Cl.**[5] **D04C 1/00**

[52] **U.S. Cl.** **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

FOREIGN PATENT DOCUMENTS

2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom .	
2218312A	11/1989	United Kingdom	A01K 91/00

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Attorney, Agent, or Firm—Hal Brent Woodrow

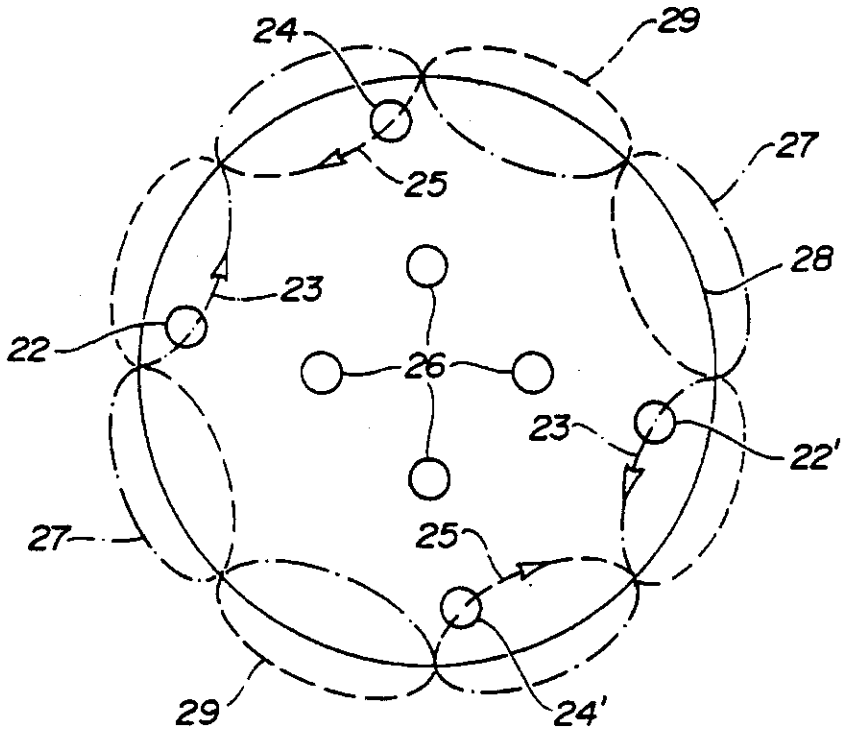
[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1



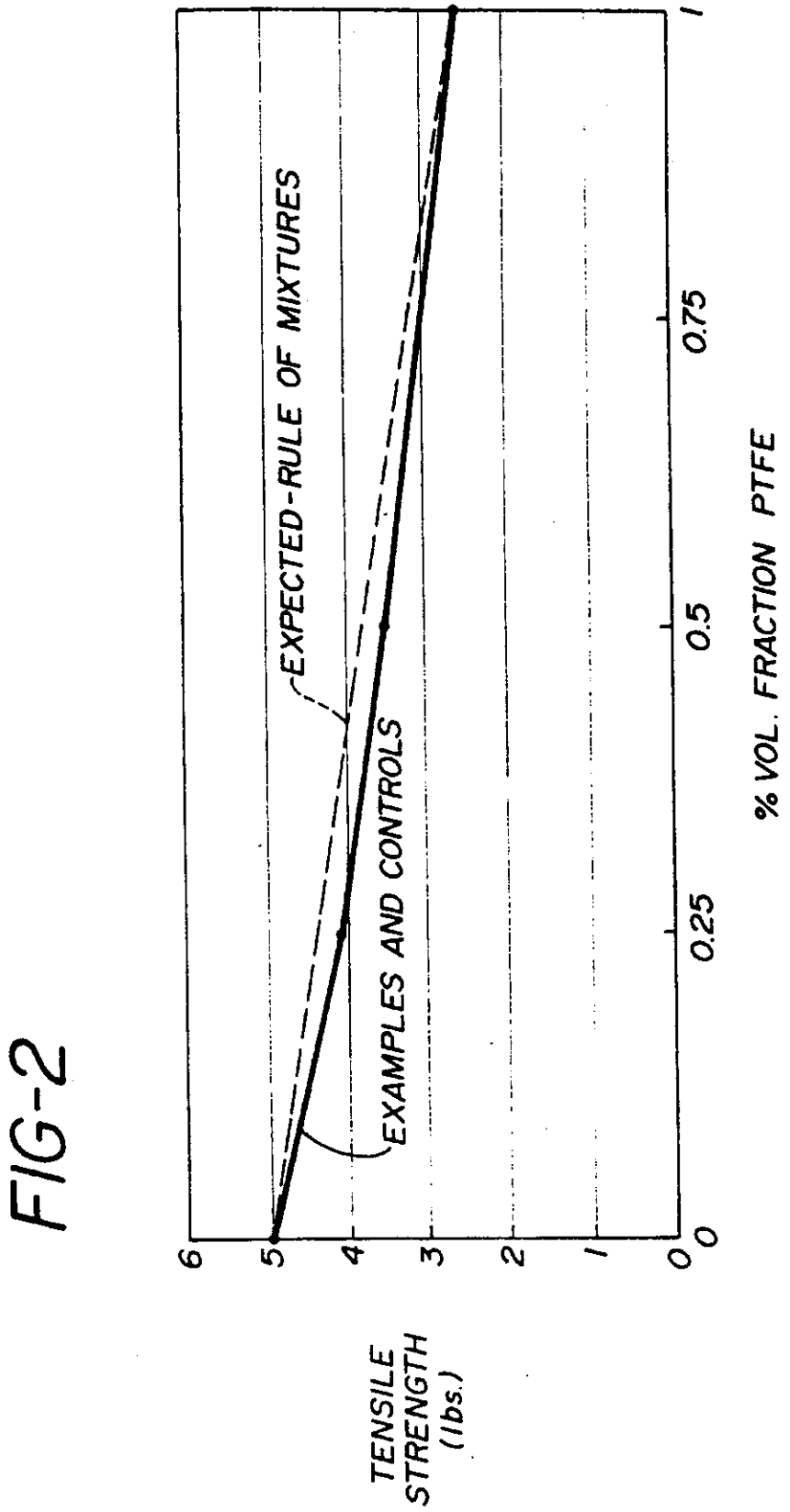
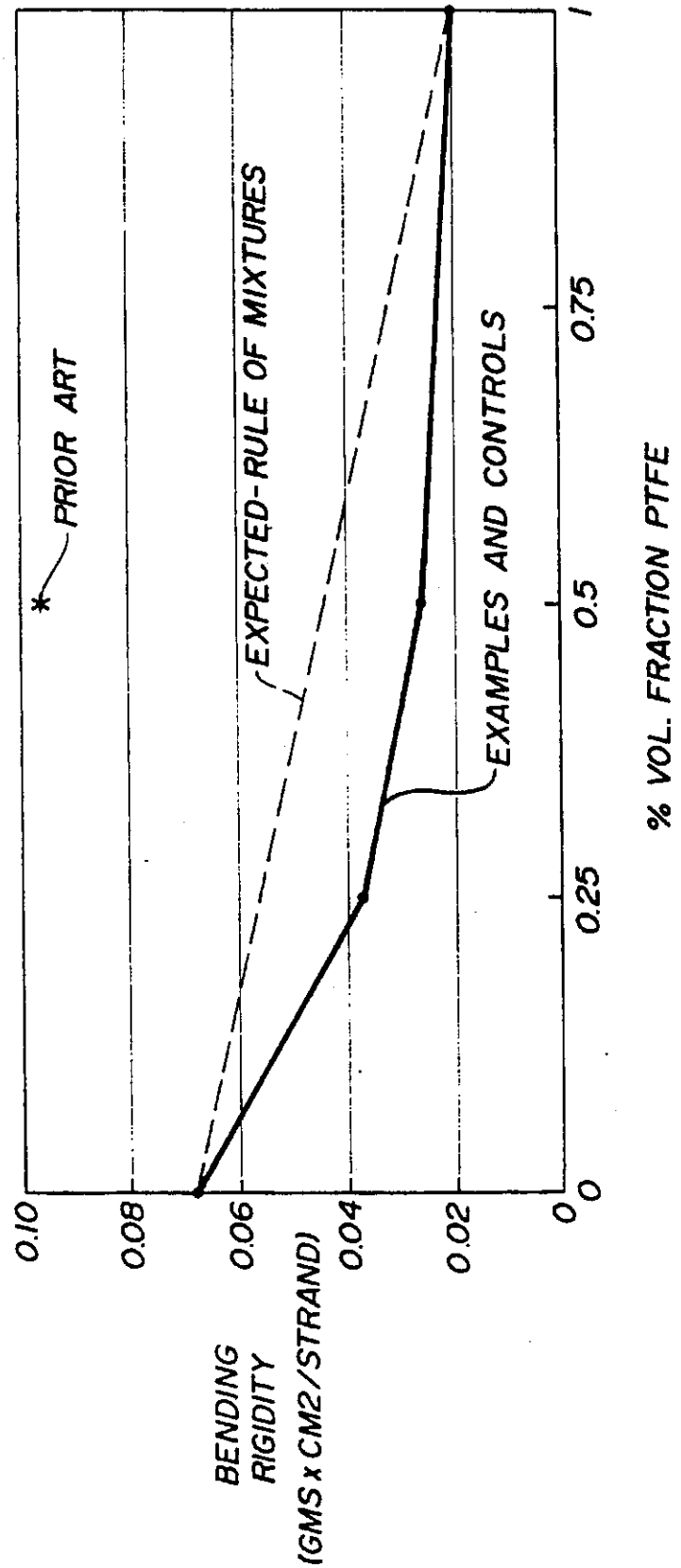

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-2

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
BENDING RIGIDITY (GMS x CM2/STRAND)
0.10
0.08
0.06
0.04
0.02
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim **1** wherein the suture is attached to a needle.

3. The surgical suture of claim **1** wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim **3** wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim **4** wherein the first set of yarns is PTFE.

6. The surgical suture of claim **5** wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim **6** wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim **1** wherein the second set of yarns is PET.

9. The surgical suture of claim **8** wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

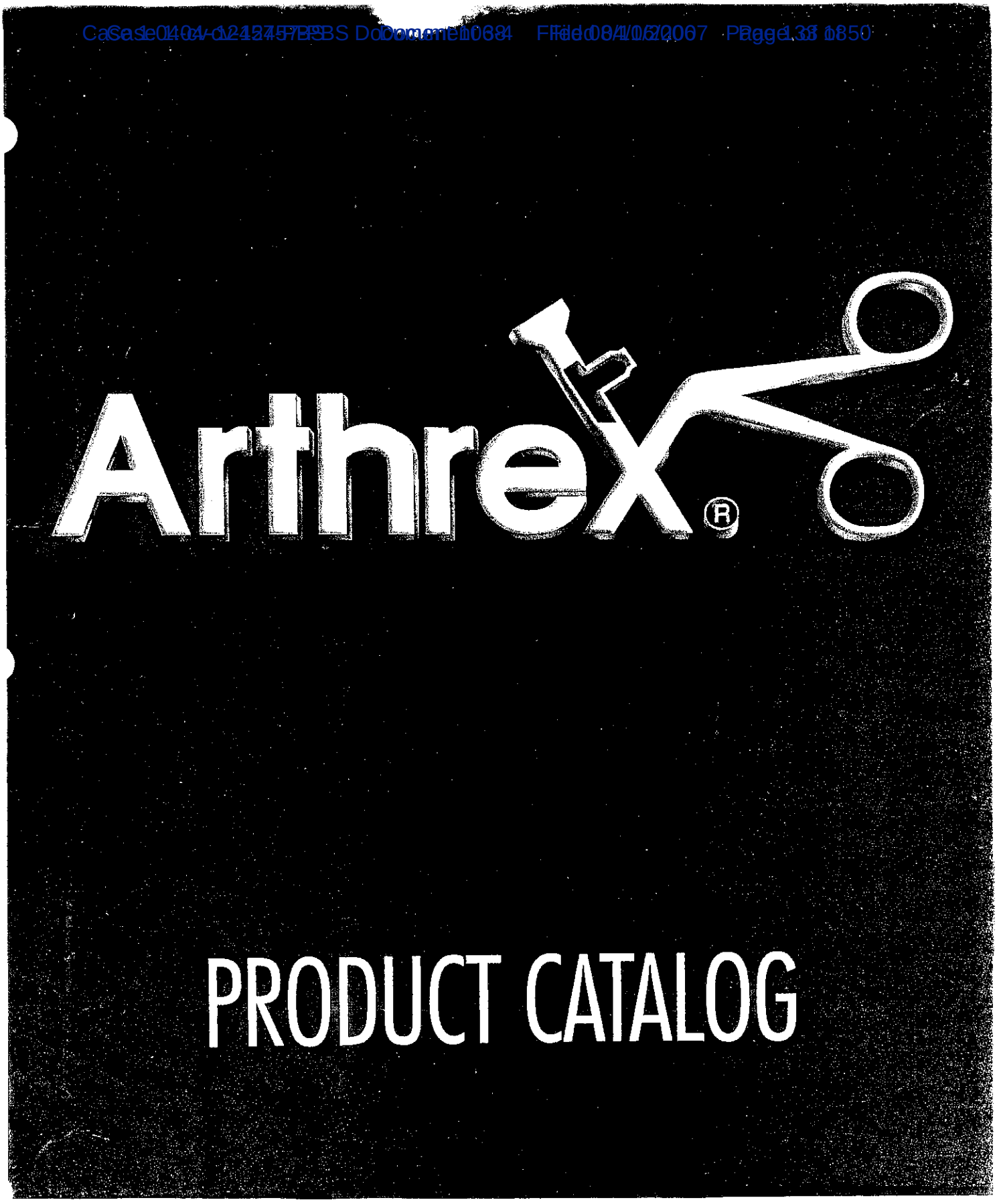
10. The surgical suture of claim **9** wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim **1** wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim **8** wherein the suture is attached to a needle.

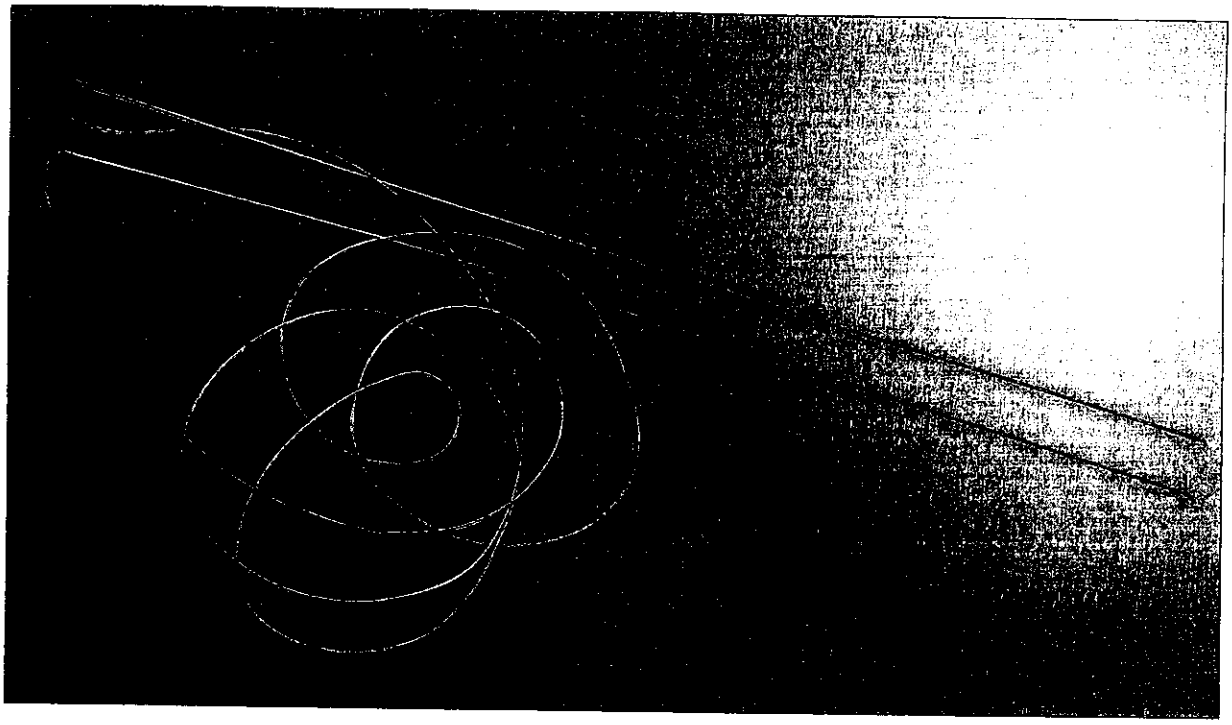
* * * * *

EXHIBIT 2



Arthrex®

2-0 FiberWire® Meniscus Repair Needles



Key Words: **Inside/out meniscus repair, 2-0 FiberWire, superior strength, smooth tie ability, lower knot profile, Joystick instrumentation**

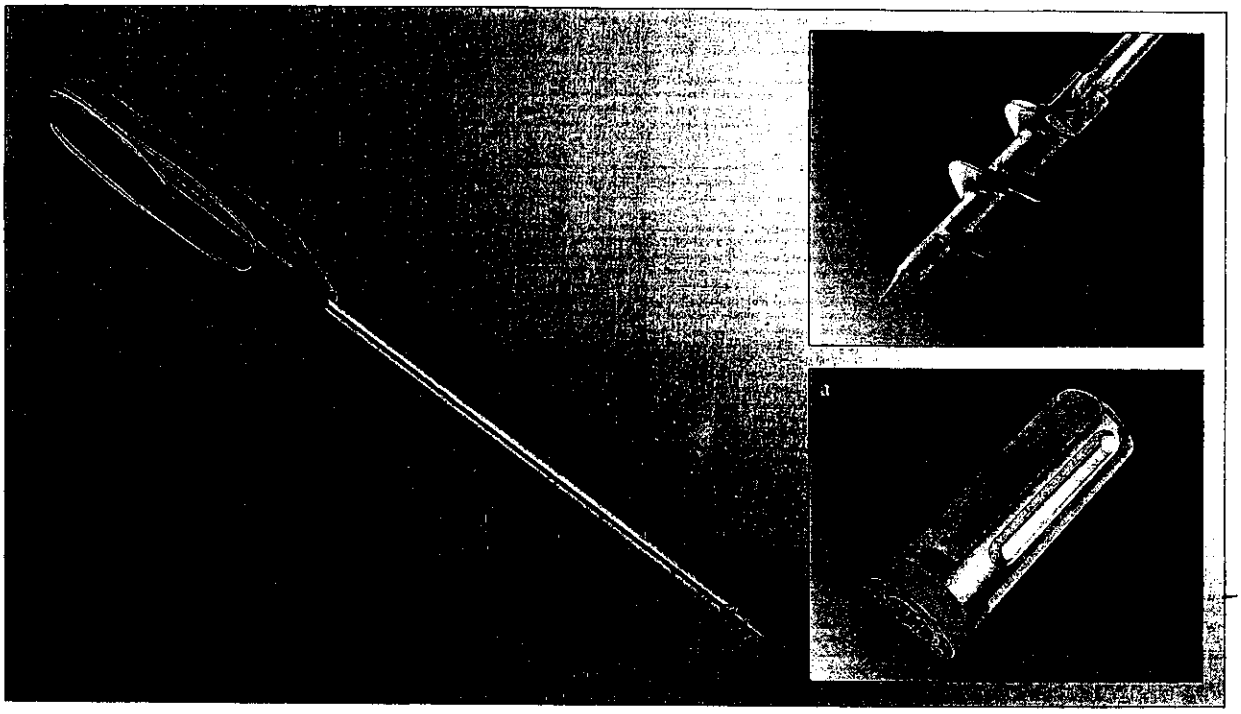
The 2-0 FiberWire Meniscus Repair Needles are made of a standard length stainless steel with a 38 inch length of 2-0 FiberWire swedged onto the back end of each needle. This allows the surgeon to perform a standard inside/out meniscus repair with all the benefits of FiberWire's superior strength, feel, abrasion resistance, smooth tie ability and lower knot profile. FiberWire virtually eliminates suture breakage during knot tying and tensioning.

These sterile meniscus repair needles and suture may be used in conjunction with the Meniscal Repair Joystick System to position optimum vertical or horizontal mattress sutures on superior or inferior meniscal surfaces. The meniscal needles also work with other meniscal repair systems.

2-0 FiberWire Meniscus Repair Needles, 2 ea., sterile, *SU* AR-7223

Arthrex®

Corkscrew™ Suture Anchor



Key Words: **Rotator cuff repair, two sutures, cancellous threads, maximum pull-out strength in soft bone, optional attachable handle, FiberWire or TigerTail option**

The Corkscrew Suture Anchor is available in 3.5 mm, 5 mm and 6.5 mm diameters that incorporate a small minor diameter and a cancellous screw thread design for maximum pull-out strength in bone. The vertical laser mark on the distal part of the insertion shaft indicates the orientation of the suture eyelets. When the anchor is inserted, the vertical laser mark should point toward the cuff tendon to ensure the suture slides smoothly through the tissue and eyelet minimizing suture abrasion and sliding resistance. The sharp, conical tip ensures that positioning on bone and ease of starting will be accomplished with little effort. The Corkscrew anchor can be inserted through a small stab incision without the need for a cannula. All Corkscrews are supplied sterile and preloaded on a disposable handled inserter with either #2 FiberWire suture or #2 Tevdek suture.

A Corkscrew Starter Awl is available should the surgeon encounter very hard bone and subsequent difficulties starting the anchor in indications other than the humeral head. This Awl requires a handle such as the Tear Drop Handle (AR-2001) or the Ratcheting Screwdriver Handle (AR-1999). A Reusable Corkscrew Handle is available for surgeons who prefer a larger handle design. All implants are sterile and *SU*.

Corkscrew Suture Anchor, 3.5 mm x 12 mm, w/handled inserter and #2 braided suture, qty. 5	AR-1915S
Corkscrew Suture Anchor, 3.5 mm x 12 mm, w/handled inserter and #2 FiberWire, qty. 5	AR-1915SF
Corkscrew Suture Anchor w/Needles, 3.5 mm x 12 mm, w/handled inserter and two size 0 FiberWire (1 blue, 1 white) (driver length for foot and ankle procedures only)	AR-1915SNF
Corkscrew Suture Anchor, 5 mm x 15.5 mm, w/handled inserter and two #2 braided sutures, qty. 5	AR-1920S
Corkscrew Suture Anchor, 5 mm x 15.5 mm, w/handled inserter and two #2 FiberWire, qty. 5	AR-1920SF
Corkscrew Suture Anchor w/Needles, 5 mm x 15.5 mm, w/handled inserter and two #2 FiberWire, qty. 5 (driver length for foot and ankle procedures only)	AR-1920SNF
Corkscrew Suture Anchor, 5 mm x 15.5 mm, w/handled inserter and two #2 TigerTail, qty. 5	AR-1920SFT
Corkscrew Suture Anchor, 6.5 mm x 15.5 mm, w/handled inserter and two #2 braided sutures, qty. 5	AR-1925S
Corkscrew Suture Anchor, 6.5 mm x 15.5 mm, w/handled inserter and two #2 FiberWire, qty. 5	AR-1925SF
Corkscrew Suture Anchor w/Needles, 5 mm x 15.5 mm, w/handled inserter and two #2 FiberWire, qty. 5	AR-1920NSF

U.S. PATENT NOS. 6,117,162; 6,214,031; 6,511,499 and 6,652,563

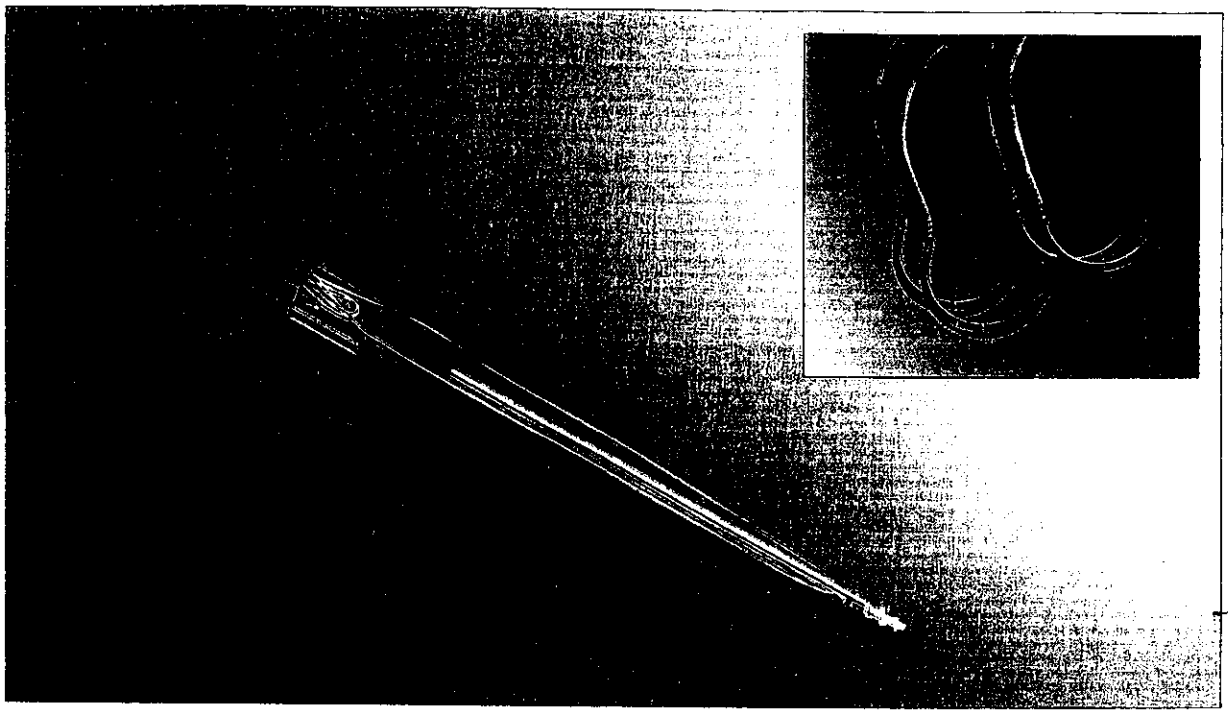
Accessories:

Reusable Corkscrew Handle (a)	AR-1927
Corkscrew Starter Awl, 3.5 mm/5 mm	AR-1915T

Actual Size of 5.0 mm

Arthrex®

Bio-Corkscrew™ Suture Anchor w/Needles



Key Words: **PLLA material, unique suture eyelet, reduced suture abrasion, maximum pull-out in cancellous bone, ideal for rotator cuff repair**

The Bio-Corkscrews with needles are also available for use when performing mini-open rotator cuff procedures. Each end of the suture comes with a 26 mm 1/2 circle, tapered cutting needle swedged-on and housed in a 'trap door' on the inserter handle.

The punch is used to create a pilot hole before the implant is inserted. In hard bone, the tap or combo punch/tap are needed. *The 6.5 mm implant should only be used in soft bone.*

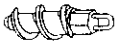
Bio-Corkscrew Suture Anchor w/Needles, 5 mm x 17.9 mm, w/handled inserter and two #2 braided sutures (1 green/1 white), sterile, qty. 5, *SU*	AR-1920BN
Bio-Corkscrew Suture Anchor w/Needles, 5 mm x 17.9 mm, w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*	AR-1920BNF
Bio-Corkscrew Suture Anchor w/Needles, 6.5 mm x 17.9 mm, w/handled inserter and two #2 braided suture (1 green/1 white), sterile, qty. 5, *SU*	AR-1925BN
Bio-Corkscrew Suture Anchor w/Needles, 6.5 mm x 17.9 mm, w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*	AR-1925BNF

Accessory Instrumentation:

Bio-Corkscrew Cutting Punch, 5 mm	AR-1920CPB
Bio-Corkscrew Combo Punch/Tap, 5 mm	AR-1920PTB
Bio-Corkscrew Combo Punch/Tap, 6.5 mm	AR-1925PTB
Bio-Corkscrew Punch, 5 mm	AR-1920PB
Bio-FASTak/Bio-Corkscrew Instrumentation Case	AR-1327

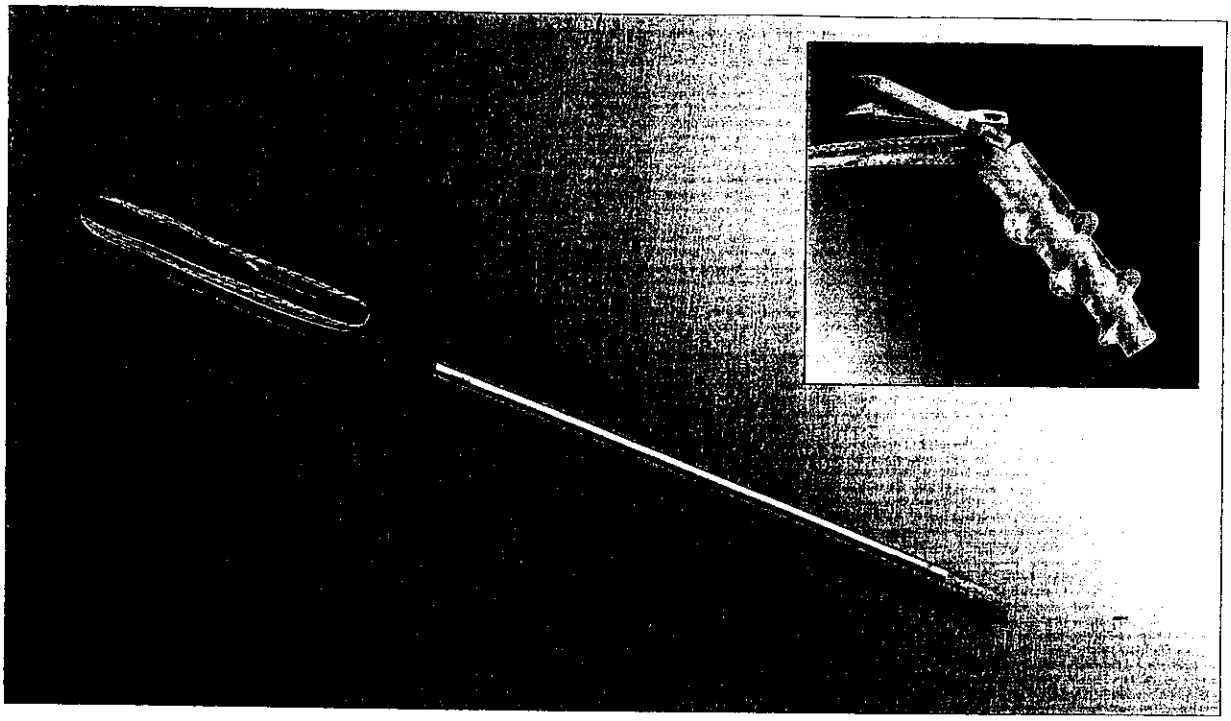
U.S. PATENT NOS. 5,964,783; 6,716,234 and PATENT PENDING

Actual Size of 5 mm



Arthrex®

Bio-Corkscrew™ Suture Anchor w/NeedlePunch Needles



Key Words: **PLLA material, unique suture eyelet, reduced suture abrasion, maximum pull-out in cancellous bone, ideal for rotator cuff repair**

The Bio-Corkscrews with NeedlePunch Needles are ideal for arthroscopic suture passing using the NeedlePunch instrument. The NeedlePunch Needles are preloaded on one end of each suture and housed inside the driver shaft. As the anchor is being inserted, ensure the laser line is adjacent to the tissue before removing the handle to ensure suture 'slide ability' for easy suture passing and knot tying.

The punch is used to create a pilot hole before the implant is inserted. In hard bone, the tap or punch/tap combo are needed. *The 6.5 mm implant should only be used in soft bone.*

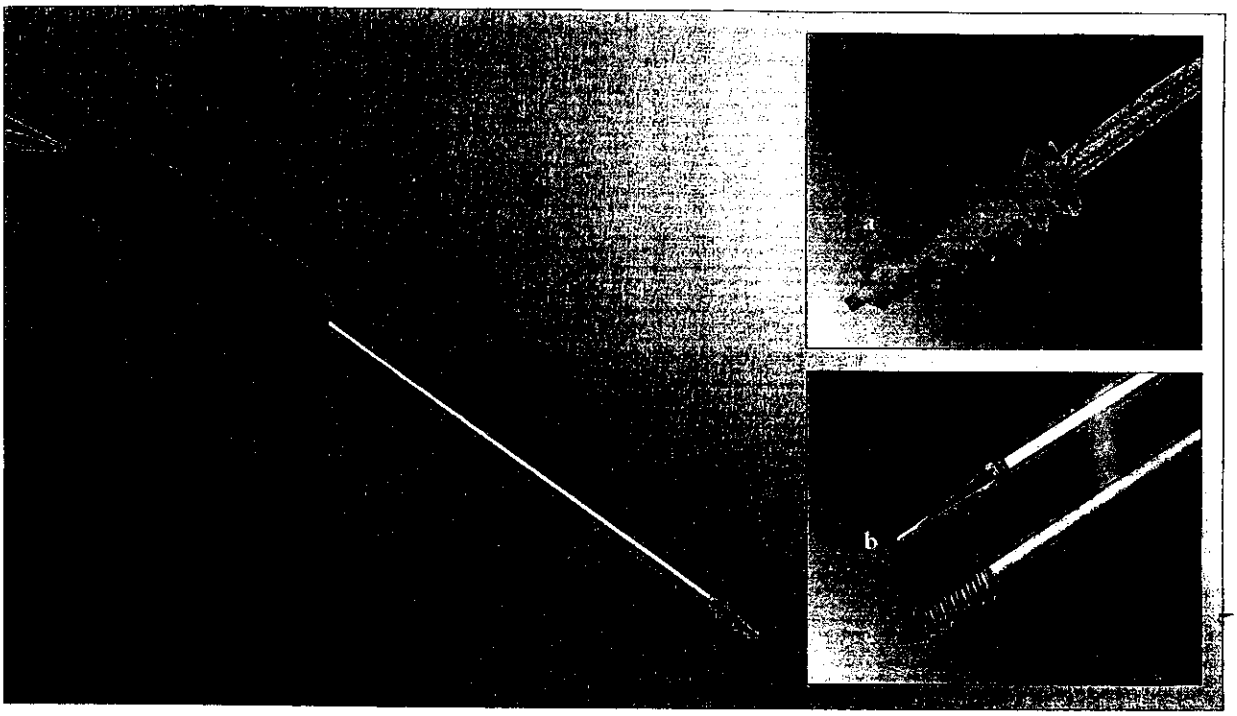
Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 5 mm x 17.9 mm, w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*	AR-1920BNP
Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 6.5 mm x 17.9 mm, w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*	AR-1925BNP
Accessory Instrumentation:	
Bio-Corkscrew Cutting Punch, 5 mm	AR-1920CPB
Bio-Corkscrew Combo Punch/Tap, 5 mm	AR-1920PTB
Bio-Corkscrew Combo Punch/Tap, 6.5 mm	AR-1925PTB
Bio-Corkscrew Punch, 5 mm	AR-1920PB
Bio-FASTak/Bio-Corkscrew Instrumentation Case	AR-1327

U.S. PATENT NOS. 5,964,783; 6,716,234 and PATENTS PENDING

Actual Size of 5 mm

Arthrex®

Bio-Corkscrew™ FT Suture Anchor



Key Words: **PLLA, rotator cuff repair, bioabsorbable suture anchor, internal FiberWire eyelet, full thread purchase of cortical bone increases strength and eliminates anchor "pull back"**

The Bio-Corkscrew FT (fully threaded) is a 5.5 mm diameter bioabsorbable suture anchor designed to be inserted flush with the cortical bone surface to maximize fixation strength and anchor stability. The fully threaded design substantially improves pull-out strength compared to suture anchors with protruding eyelets. The fully threaded design prevents anchor "pull-back" that may occur with countersunk anchors, which is especially advantageous when poor quality bone is encountered.

The Bio-Corkscrew FT has a unique FiberWire eyelet recessed into the body of the anchor which reduces suture abrasion at the eyelet during knot tying.

The Bio-Corkscrew FT's strong internal square head drive mechanism substantially increases resistance to stripping during insertion to hard cortical bone. The Bio-Corkscrew Punch is always used to prepare a bone socket prior to insertion of the anchor. In most cases, no tapping will be needed prior to the anchor being implanted. When extreme cortical bone is present, the Cutting Tap for Bio-Corkscrew FT is used.

The Bio-Corkscrew FT comes preloaded with two #2 FiberWire sutures, one blue and one white/black, for easier suture management. The implant is also available with two 26 mm 1/2 circle cutting needles swedged on each suture for open procedures.

Bio-Corkscrew FT Suture Anchor, 5.5 mm x 15 mm, w/ two #2 FiberWire, sterile, qty. 5, *SU* (a)	AR-1927BF
Bio-Corkscrew FT Suture Anchor w/ Needles, 5.5 mm x 15 mm, w/ two #2 FiberWire with 26 mm 1/2 circle needles, sterile, qty. 5, *SU*	AR-1927BNF

U.S. PATENT NOS. 5,964,783; 6,716,234 and PATENT PENDING

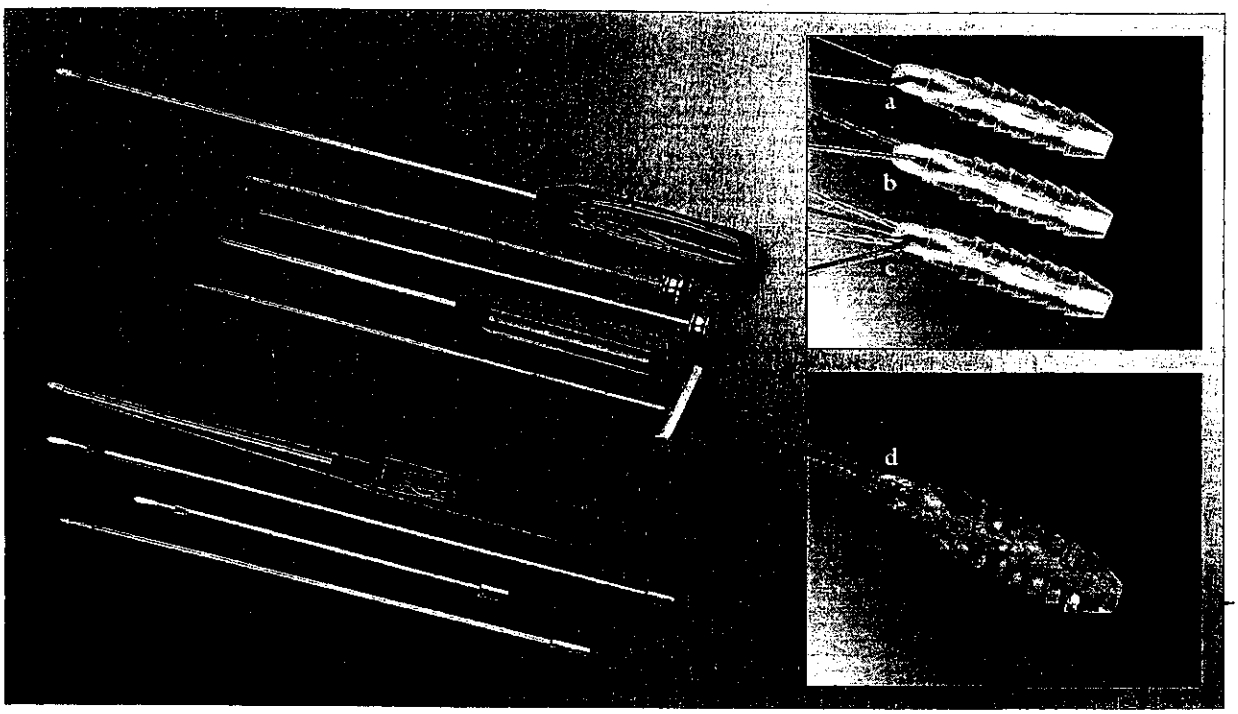
Required Instrumentation:

Bio-Corkscrew Punch, 5 mm	AR-1920PB
Bio-Corkscrew Cutting Punch, 5 mm (b)	AR-1920CPB
Cutting Tap for Bio-Corkscrew FT (c)	AR-1927CTB

Actual Size of 5.5 mm

Arthrex®

Bio-SutureTak™ Suture Anchor



Key Words: **Push-in bioabsorbable suture anchor, plication suture option, molded-in suture eyelet eliminates suture abrasion**

The Bio-SutureTak is a 3 mm bioabsorbable "push-in" suture anchor with a molded-in suture eyelet ideal for soft tissue attachment to bone in the shoulder joint and other indications where a small anchor profile with high pull-out strength is required. The exclusive braided suture eyelet loop is molded into the body of the anchor and provides superior resistance to suture abrasion compared to conventional metal anchors. This unique eyelet design allows the attached suture to slide smoothly enhancing the performance of arthroscopic sliding-knots. The Bio-SutureTak is available with either one or two #2 FiberWire sutures or with one polyester Tevdek suture. For use in softer bone and revisions, the Bio-SutureTak is also available in a 3.7 mm diameter. All of the Bio-SutureTaks are sterile, single use and preloaded on a disposable handled inserter for speed and convenience.

A needle version of the Bio-SutureTak is also available. It is recommended that the optional Short Spade Tip Drill and optional Short Spear be used with the Bio-SutureTak w/Needles. The Spear with Trocar and Blunt Obturator is used for percutaneous insertion or through a cannula. A Blunt Tip Obturator is also in the instrument set. The Bio-SutureTak Punch can be used to make a small pilot hole and to provide a coined surface to avoid skiving of the drill which is always used. Two other cannulated inserters are available: the Offset Clear Guide and the Clear Guide.

Implants and Accessories:

Bio-SutureTak, 3 mm x 14 mm, qty. 5 *(a)*	AR-1934B
Bio-SutureTak w/#2 FiberWire, 3 mm x 14 mm, qty. 5	AR-1934BF
Bio-SutureTak w/two #2 FiberWire, 3 mm x 14 mm, qty. 5 *(c)*	AR-1934BF-2
Bio-SutureTak w/#2 TigerTail, 3 mm x 14 mm, qty. 5 *(b)*	AR-1934BFT
Bio-SutureTak w/Needles, 3 mm x 14 mm, w/#2 FiberWire, qty. 5	AR-1934BNF
Bio-SutureTak, 3.7 mm x 14 mm, w/#2 FiberWire, qty. 5 (d)	AR-1934BLF
Short Spade Tip Drill *(use with AR-1326G)*	AR-1256
Spade Tip Drill, thick shaft	AR-1252
Spade Tip Drill	AR-1257
Short Spear *(used with AR-1256)*	AR-1326G
Plication Driver, sterile, *SU*	AR-1934DBS
Step Drill *(for 3 mm Bio-SutureTak) (required)*	AR-1250LT
Step Drill for 3.7 mm Bio-SutureTak *(required)*	AR-1908
Clear Guide, sterile, *SU*	AR-1934CG
Offset Clear Guide, sterile, *SU*	AR-1934G
Bio-SutureTak Disposables Kit, sterile, *SU*	AR-1934DS
Bio-SutureTak Disposables Kit, w/metal Spear	AR-1934DS-2

U.S. PATENT NO. 6,716,234 and PATENT PENDING

Bio-SutureTak Instrumentation Set, 3 mm (AR-1934S):

Spear with Trocar and Blunt Obturator	AR-1949
Blunt Tip Obturator	AR-1949-02
Bio-SutureTak Punch	AR-1934P
Bio-SutureTak Instrumentation Case	AR-1934C

Bio-SutureTak Instrumentation Set, 3.7 mm (AR-1934LS):

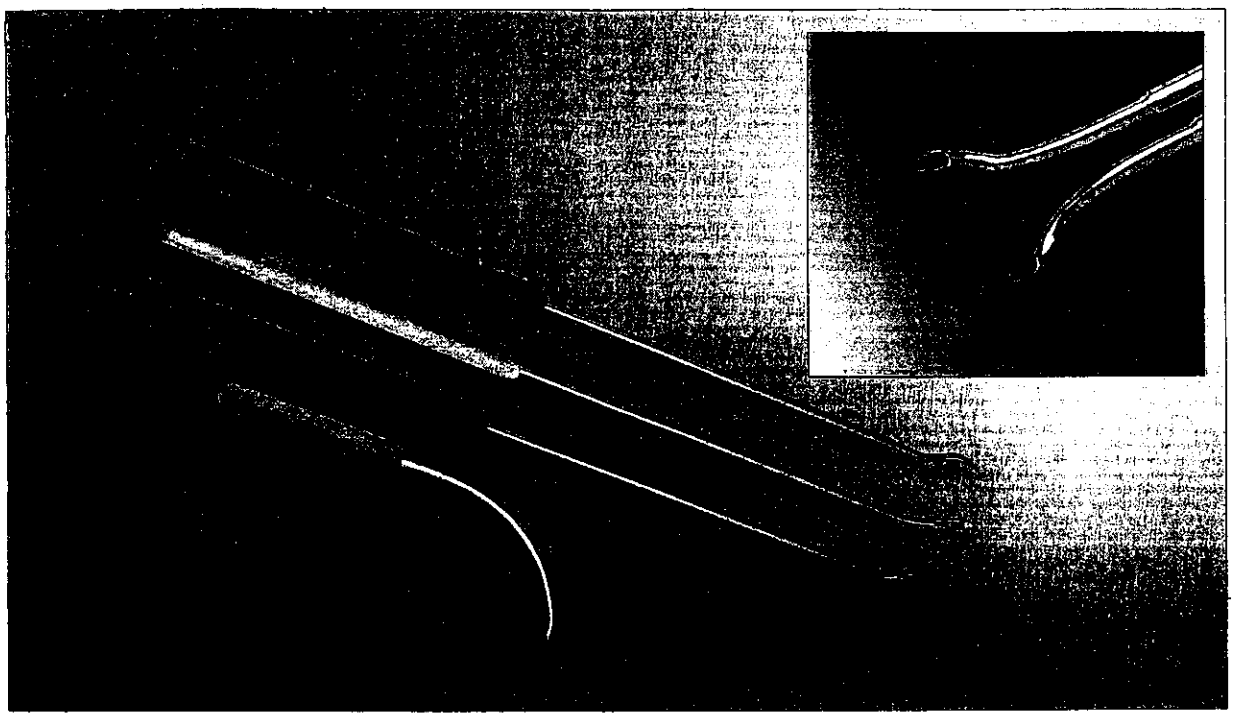
Bio-SutureTak Spear, 3.7 mm, reusable	AR-1907
Bio-SutureTak Instrumentation Case	AR-1934C

U.S. PATENT NO. 6,716,234 and PATENT PENDING

Actual Size of 3 mm

Arthrex®

SutureLasso™



Key Words: **Arthroscopic shoulder repairs, less technically demanding, facilitates soft tissue suture placement, reproducible and accurate, single use, Nitinol loop**

The SutureLasso is a single use suture shuttle instrument available in various curved tip configurations for arthroscopic Bankart, SLAP and rotator cuff repairs. Each Lasso comes preloaded with a Nitinol loop. The sharp tip and small diameter shaft will easily penetrate soft tissue while the reinforced shaft resists bending. After the tip is passed through soft tissue, the loop is deployed and retrieved through a cannula with a Crochet Hook or Suture Retriever. A suture strand or suture tail from a previously placed suture anchor is placed in the loop, and the opposite end of the loop is pulled, delivering the suture through tissue and out the cannula. The Corkscrew SutureLasso, 45° curve right, should be used for anterior labral reconstruction of the right shoulder.

The Banana SutureLasso is designed for rotator cuff suturing from a superior, percutaneous approach (Modified Neviaser Portal).

Banana SutureLasso, sterile, *SU*	AR-4065B
SutureLasso, 45° w/Wire Loop, sterile, *SU*	AR-4065W
SutureLasso, 90° w/Wire Loop, sterile, *SU*	AR-4065-90W
Corkscrew SutureLasso, 45° curve right, sterile, *SU*	AR-4065-45R
Corkscrew SutureLasso, 45° curve left, sterile, *SU*	AR-4065-45L

Designed in conjunction with Stephen S. Burkhart, M.D., San Antonio, TX, and James E. Tibone, M.D., Inglewood, CA.

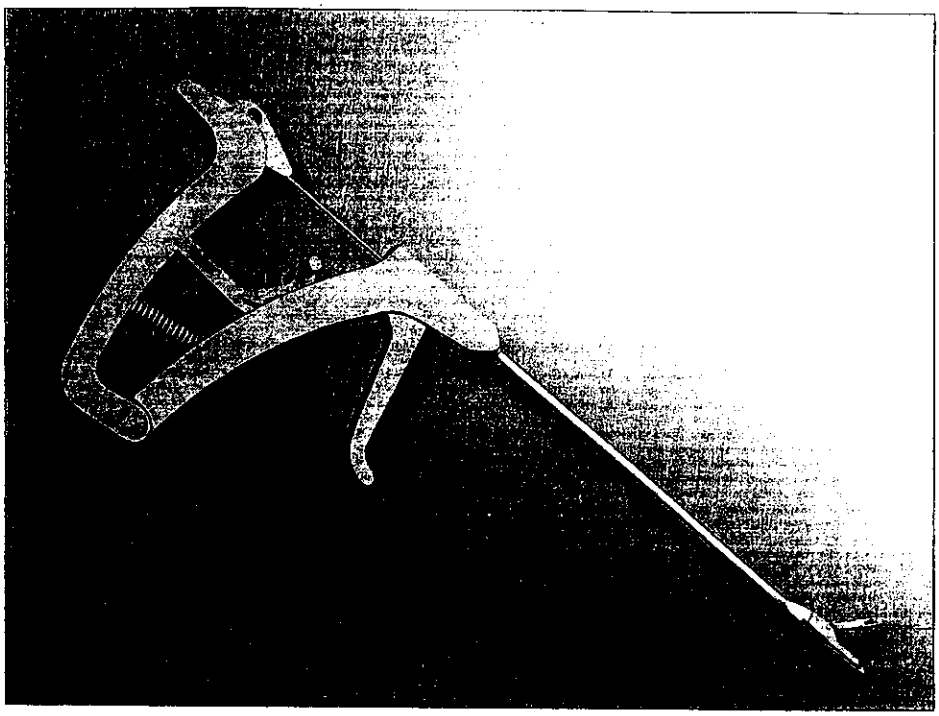
Recommended Accessories:

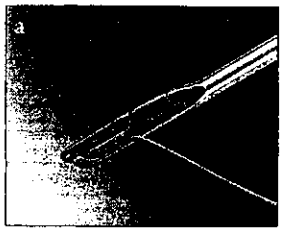
Crochet Hook	AR-5008H
Push/Pull Crochet Hook	AR-5009H
Suture Retriever, 3.4 mm, straight	AR-12540
Suture Retriever, 3.4 mm, 15° up	AR-12550
Suture Retriever, 3.4 mm, 45° right	AR-12580
Suture Retriever, 3.4 mm, 45° left	AR-12590
KingFisher Suture Retriever/Tissue Grasper	AR-13970SR
FiberStick, #2 FiberWire, 50 inches (blue) one end stiffened, 12 inches, sterile, qty. 5, *SU*	AR-7209
#2 TigerStick, #2 TigerWire, 50 inches (white/black) one end stiffened, 12 inches, sterile, qty. 5, *SU*	AR-7209T
2-0 FiberStick, 2-0 FiberWire, 50 inches (blue) one end stiffened, 12 inches, sterile, qty. 5, *SU*	AR-7222

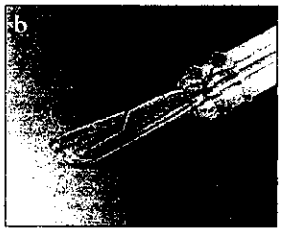
PATENT PENDING

Arthrex®

NeedlePunch™ II







Key Words: **Arthroscopic needle passing, simple, reproducible suture passing, 7 mm cannula, precisely engineered, lifetime guarantee**

The NeedlePunch II is a simple, versatile and effective suture passing instrument with a new ergonomic handle and push rod. The low profile design allows it to fit through a 7 mm diameter cannula. The lower jaw has more taper for easier placement under the rotator cuff tissue. The instrument enables the surgeon to reduce soft tissue and place a stitch up to 1 cm medial to the edge of the tissue in one quick step.

The NeedlePunch needle comes pre-loaded on Bio-Corkscrew Suture Anchors for suture passing without a shuttle step. The FiberWire Loop with NeedlePunch needle is a #2 FiberWire suture with a loop at the end to shuttle an anchor suture through soft tissue. The NeedlePunch Suture Shuttle is a NeedlePunch needle with a small loop of 2-0 FiberWire attached allowing direct passage of the anchor suture through tissue. The #2 FiberWire with two NeedlePunch needles is for side-to-side rotator cuff repairs.

A needle is loaded into the bottom jaw of the instrument and the back handle is squeezed slightly locking the needle into place. Once the desired bite of tissue is grasped, deploy the needle through the cuff by squeezing the back handle. The needle comes up through the soft tissue and locks into the catch mechanism on the upper jaw. To remove the needle, open the jaw and remove the needle by sliding it towards the hinge.

NeedlePunch II	AR-13981S
NeedlePunch II Push Rod Replacement	AR-13981P

NeedlePunch Accessories:

FiberWire Loop w/Needle for NeedlePunch, 26 inches, sterile, qty. 12, *SU*	AR-7204
#2 FiberWire w/two Needles for NeedlePunch, sterile, qty. 12, *SU*	AR-7207
Suture Shuttle, 40 mm, sterile, qty. 5, *SU*	AR-7224
Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 5 mm x 17.9 mm, w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*	AR-1920BNP
Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 6.5 mm x 17.9 mm, w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*	AR-1925BNP

U.S. PATENT NO. 6,716,234 and PATENT PENDING

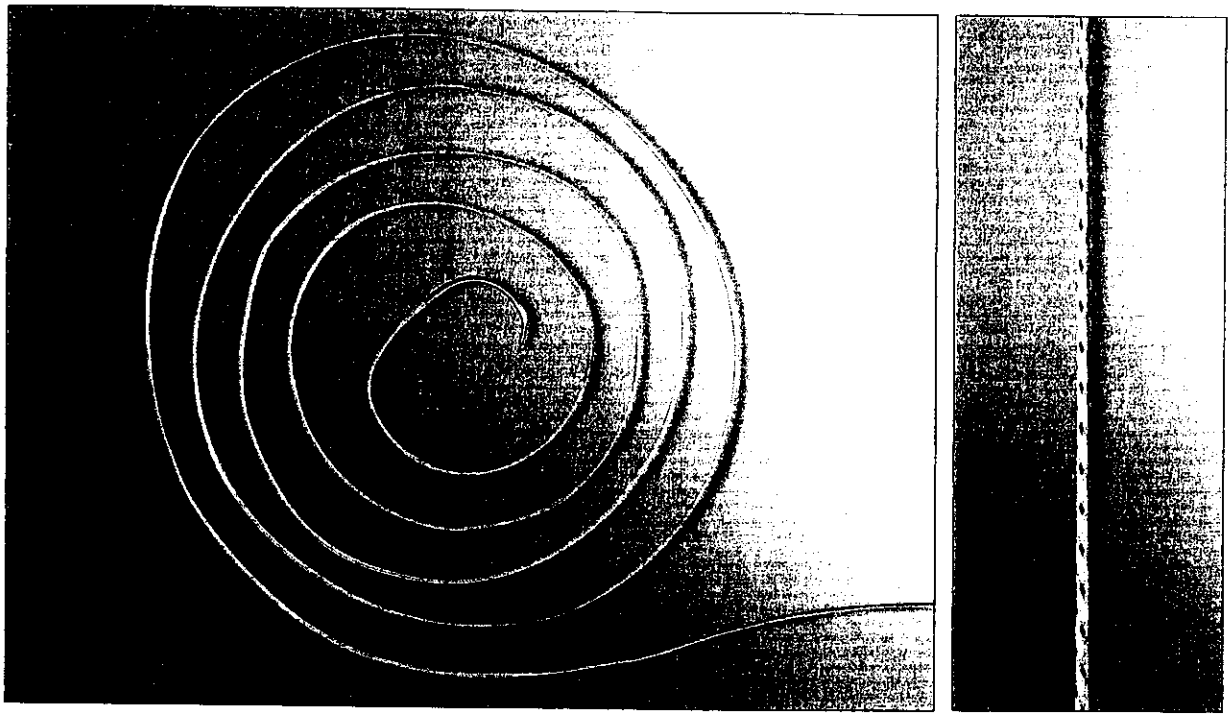
Recommended Cannula:

Partially Threaded Cannula, 7 mm x 7 cm, sterile, qty. 5, *SU*	AR-6567

Designed in conjunction with John K. Morris, M.D., Ann Arbor, MI, and Stephen S. Burkhart, M.D., San Antonio, TX.

Arthrex®

FiberWire® and TigerWire®



Key Words: **Size #2 with the strength of #5, new composite material technology, abrasion resistant, designed for most orthopaedic reconstruction procedures**

FiberWire suture is a new generation of polyester suture with a long chain polyethylene core. FiberWire has greater strength than similar sized polyester suture with superior feel, smooth tie ability and lower knot profile. FiberWire is the ideal suture for most orthopaedic soft tissue repairs, virtually eliminating suture breakage during knot tying.

#2 TigerWire, a white suture with black spiral markings, was created specifically for arthroscopic surgeons that require superior suture visibility, easier arthroscopic orientation and motion determination.

All sizes of FiberWire have greater strength than polyester suture with the same diameter, with smoother feel and tie ability. Cyclic loading of #2 FiberWire resulted in 1,000,000 cycles without failure compared to 160,000 cycles of standard #2 polyester to failure. All FiberWire and TigerWire are sterile and single use.

#2 FiberWire, 38 inches (blue) w/Tapered Needle, 26.5 mm 1/2 circle, qty. 12	AR-7200
#2 FiberWire, 38 inches, 2 strands (1 blue, 1 white/black), qty. 12	AR-7201
#2 FiberWire, 38 inches (blue) w/Reverse Cutting Needle, 36.6 mm 1/2 circle, qty. 12	AR-7202
#2 TigerWire, 38 inches (white/black), qty. 12 (a)	AR-7203
#2 FiberWire, 38 inches (blue) w/two Tapered Needles, 26.5 mm 1/2 circle, qty. 12	AR-7205
#2 TigerWire, 38 inches (white/black) w/two Tapered Needles, 26.5 mm 1/2 circle, qty. 12	AR-7205T
#2 FiberWire, 38 inches (1 blue, 1 white/black) w/Tapered Needle, 26.5 mm 1/2 circle, qty. 12	AR-7208
#5 FiberWire, 38 inches (blue), qty. 12	AR-7210
#5 FiberWire, 38 inches w/Conventional Cutting Needle, 48 mm 1/2 circle, qty. 12	AR-7211
2-0 FiberWire, 18 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle, qty. 12	AR-7220
2-0 FiberWire, 38 inches (blue), qty. 12	AR-7221
3-0 FiberWire, 18 inches (blue) w/Diamond Point Needle, 26.2 mm 3/8 circle, qty. 12	AR-7225
3-0 FiberWire, 18 inches (blue) w/Tapered Needle, 15 mm 3/8 circle, qty. 5	AR-7227-01
3-0 FiberWire, 18 inches (blue) w/RC Needle, 16.3 mm 3/8 circle, qty. 5	AR-7227-02
4-0 FiberWire, 18 inches (blue) w/ Diamond Point Needle, 18.7 mm 3/8 circle, qty. 12	AR-7228
4-0 FiberWire, 18 inches (blue) w/Tapered Needle, 12.3 mm 3/8 circle, qty. 5	AR-7230-01
4-0 FiberWire, 18 inches (blue) w/RC Needle, 11.9 mm 3/8 circle, qty. 5	AR-7230-02
0 FiberWire, 38 inches (blue) w/Tapered Needle, 22.2 mm 1/2 circle, qty. 5	AR-7250
0 FiberWire, 38 inches (blue) w/Diamond Point Needle, 22.2 mm 1/2 circle, qty. 5	AR-7251

U.S. PATENT NO. 6,716,234

Arthrex®

FiberWire® Suture Kit

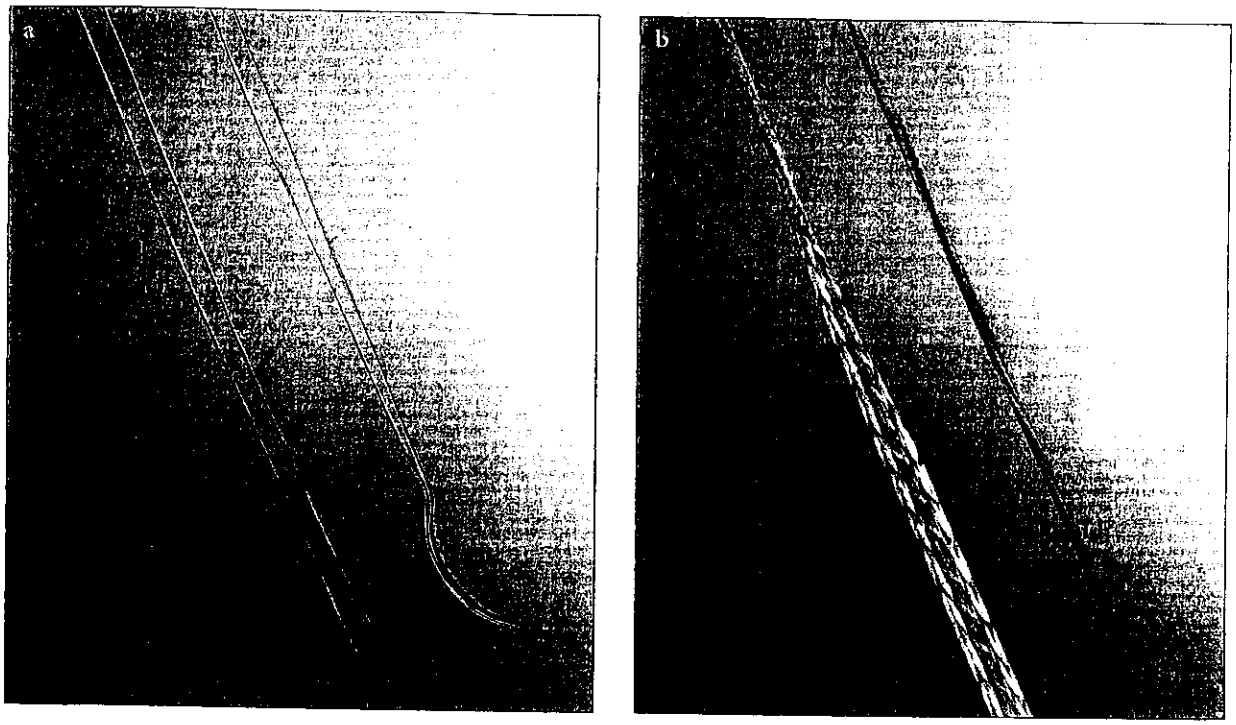
Key Words: **Convenient, compact, variety of sizes, easy suture differentiation**

The FiberWire Suture Kit is available for larger complex soft tissue approximation procedures. This kit contains a total of 18 sutures including three different colored versions of #5 FiberWire for easy suture differentiation, large cutting Spring Eye Free Needles, and #2 FiberWire in one convenient package.

FiberWire Suture Kit (AR-7219) sterile, *SU* includes:
- #5 FiberWire, 38 inches (blue), qty. 4
- #5 FiberWire, 38 inches (white), qty. 4
- #5 TigerWire, 38 inches (white/black), qty. 4
- #2 FiberWire, 38 inches (blue) w/ Tapered Needle, qty. 6
- Free Needle, Spring Eye, 80 mm, qty. 2
- Free Needle, Spring Eye, 60 mm, qty. 1

U.S. PATENT NO. 6,716,234

Arthrex®



Key Words: **Size 4-0 FiberWire, swedged-on tapered needle**

FiberLoop is a suture option for multi-strand tendon repairs. These small diameter looped FiberWire products allow for strong multi-strand flexor and extensor tendon repairs while reducing tendon damage from multiple needle passes. FiberLoop is available with multiple needle options to prevent cutting suture while stitching.

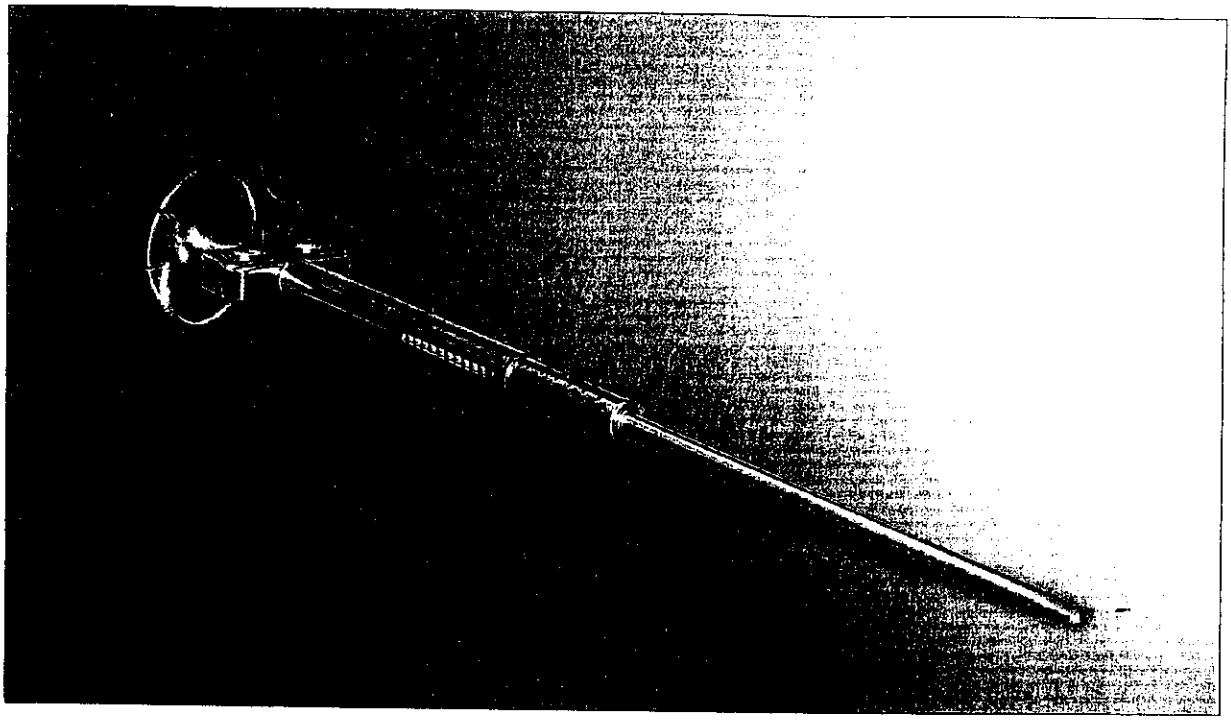
FiberTape is an ultra-high strength 2 mm width tape using the long chain polyethylene structure of the FiberWire suture. The broad footprint of the FiberTape is appropriate for repairs in degenerative cuff tissue where tissue pull-through may be a concern.

4-0 FiberLoop, 4-0 FiberWire, 12 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle, sterile, qty. 12, *SU (a)*	AR-7229-12
4-0 FiberLoop, 4-0 FiberWire, 20 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle, sterile, qty. 12, *SU*	AR-7229-20
2-0 FiberLoop, 60 inches (blue) w/Diamond Point Needle, 48 mm 1/2 circle, sterile, qty. 12, *SU*	AR-7232-01
2-0 FiberLoop, 48 inches (blue) w/Diamond Point Needle, 26.2 mm 3/8 circle, sterile, qty. 12, *SU*	AR-7232-02
2-0 FiberLoop, 30 inches (blue) w/Diamond Point Straight Needle, 64.8 mm, sterile, qty. 12, *SU*	AR-7232-03
FiberTape, 2 mm, 54 inches (blue) each end tapered to #2 FiberWire, 8 inches, sterile, qty. 12, *SU (b)*	AR-7237

U.S. PATENT NO. 6,716,234

Arthrex®

FiberWire® Tensioner



Key Words: **Arthroscopic FiberWire tensioning, open procedures**

The FiberWire Tensioner provides controlled tensioning of FiberWire loops during knot tying when reapproximating bone-to-bone or soft tissue-to-bone. The blunt tip keeps the knot in place while the tensioning wheel and spring mechanism gently tension the loop to tighten the repair. It is ideal for use in conjunction with #5 FiberWire during tuberosity reapproximation of proximal humerus fractures, patellar fracture reduction and fixation, and olecranon fracture reduction and fixation.

It is recommended that the FiberWire Tensioner be used in conjunction with sliding knots. Once the FiberWire is passed through all planes of tissue/bone, the appropriate sliding knot is tied and advanced to the tissue level. One limb of the FiberWire suture is passed up through the cannulation of the FiberWire Tensioner shaft, with the aid of a Suture Passing Wire, and loaded into the slot and locking post on the tensioning wheel to keep it in place. The tensioning wheel is then turned in a counterclockwise fashion as the tension meter is read. Once the desired amount of tension/reduction is achieved, three reverse half-hitches can be thrown down the barrel of the tensioner to secure the fixation.

FiberWire Tensioner	AR-1929

PATENT PENDING

Designed in conjunction with Anthony A. Romeo, M.D., Chicago, IL.

Accessories:

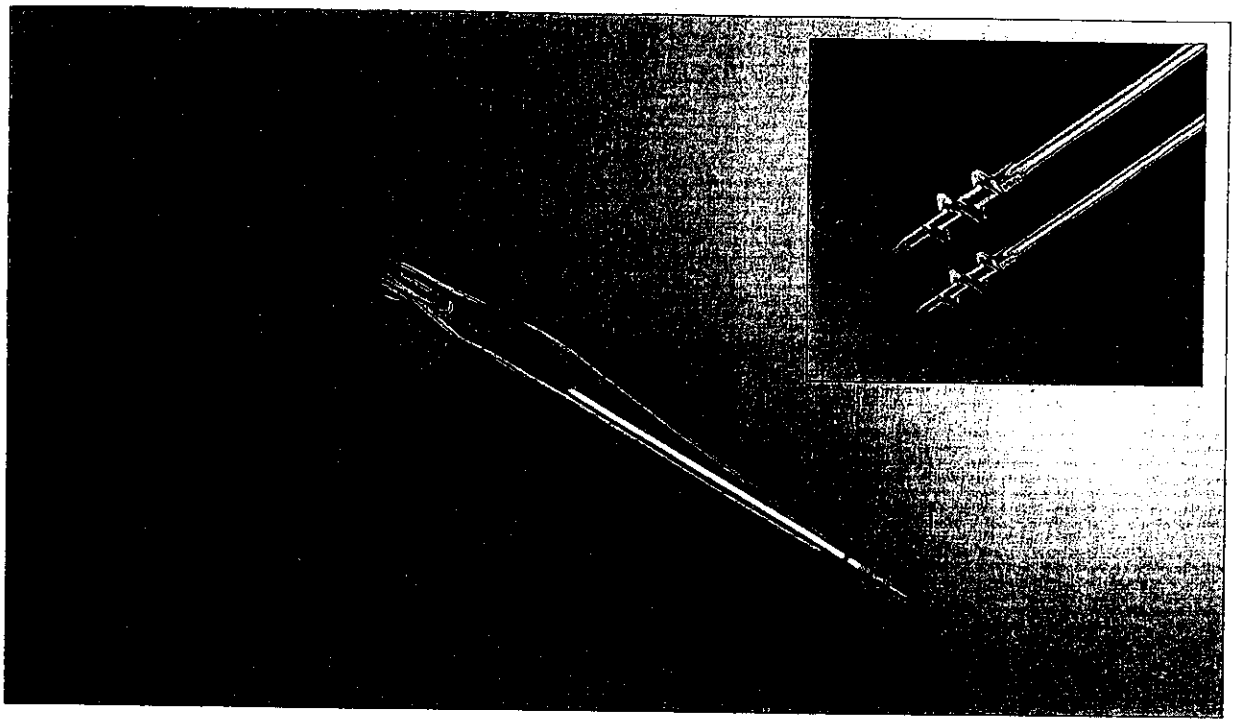
Suture Passing Wire, sterile, *SU*	AR-1255-18
FiberWire Suture Kit, sterile, *SU*	AR-7219

Recommended Suture *(sterile, SU)*:

#2 FiberWire, 38 inches w/Tapered Needle, 26.5 mm 1/2 circle, qty. 12	AR-7200
#2 FiberWire, 38 inches, 2 strands (1 blue, 1 white/black), qty. 12	AR-7201
#2 FiberWire, 38 inches w/Reverse Cutting Needle, 36.6 mm 1/2 circle, qty. 12	AR-7202
#5 FiberWire, 38 inches, qty. 12	AR-7210
#5 FiberWire, 38 inches w/Conventional Cutting Needle, 48 mm 1/2 circle, qty. 12	AR-7211

Arthrex®

Small Joint Corkscrew™ Suture Anchor



Key Words: **Soft tissue anchoring, open foot and ankle repair and reconstruction, Achilles, posterior tibial tendon, Kidner, Brostrom, lateral ankle stabilization, biceps repair, cancellous threads, FiberWire, two sutures, two needles**

The Small Joint Corkscrew is available in 3.5 mm and 5 mm diameters. They are specifically designed with shorter inserter shafts, FiberWire and needles for open procedures of the foot, ankle, hand, wrist and elbow. They incorporate a small minor diameter with a cancellous thread pattern that maximizes pull-out strength. The sharp conical tip ensures positioning on bone and ease of starting will be accomplished with little effort. A horizontal laser mark visible on the driver shaft indicates when the anchor is fully seated in the bone. The anchors are supplied sterile with two strands of FiberWire, each with diamond tip needles.

A Corkscrew Starter Awl is available should the surgeon encounter very hard bone. The awl requires either the Tear Drop Handle (AR-2001) or the Ratcheting Screwdriver Handle (AR-1999). A Reusable Corkscrew Handle is available for surgeons who prefer a larger handle design.

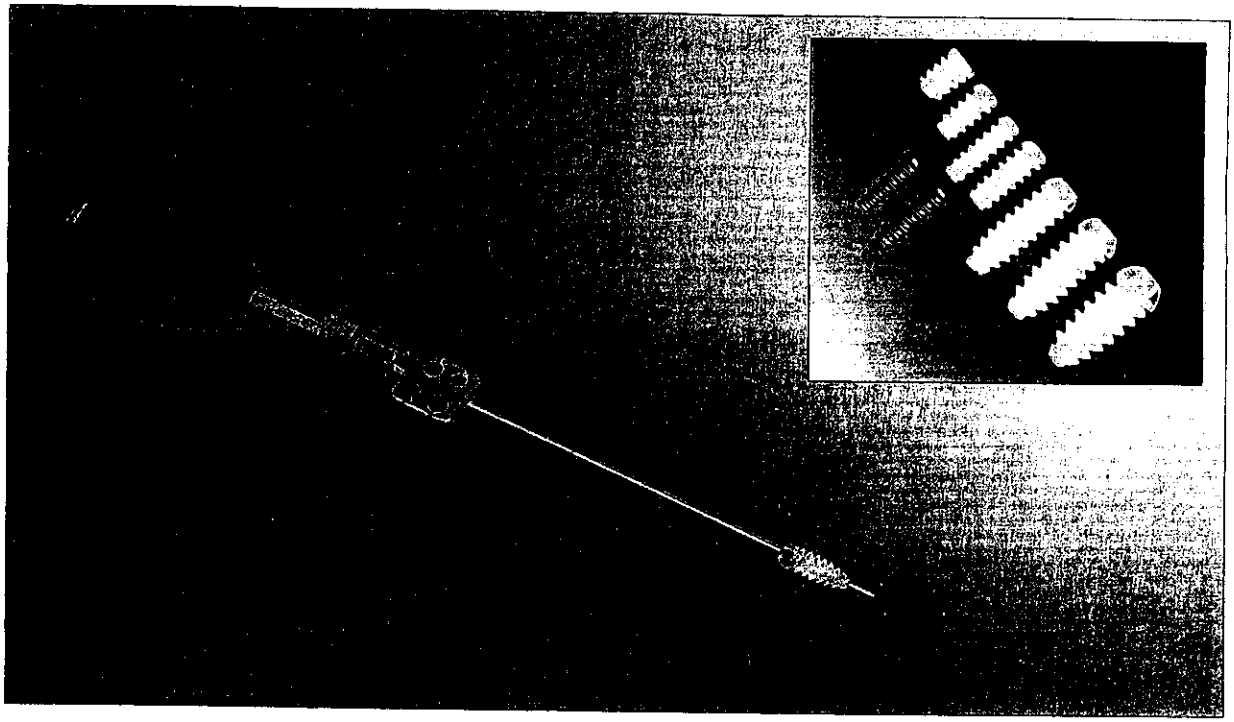
Corkscrew Suture Anchor w/Needles, 3.5 mm x 15 mm, w/handled inserter and two #0 FiberWire, sterile, qty. 5, *SU*	AR-1915SNF
Corkscrew Suture Anchor w/Needles, 5.0 mm x 15 mm, w/handled inserter and two #2 FiberWire, sterile, qty. 5, *SU*	AR-1920SNF

U.S. PATENT NOS. 6,117,162; 6,214,031 and 6,511,499

Actual Size of 5.0 mm

Arthrex®

Tenodesis™ Screws and Disposables



Key Words: **Bioabsorbable PLLA Screw, ligament or tendon-to-bone repairs, eliminates transosseous tunnel graft tensioning, biceps tenodesis, collateral ligament repairs and reconstructions, ACL backup fixation**

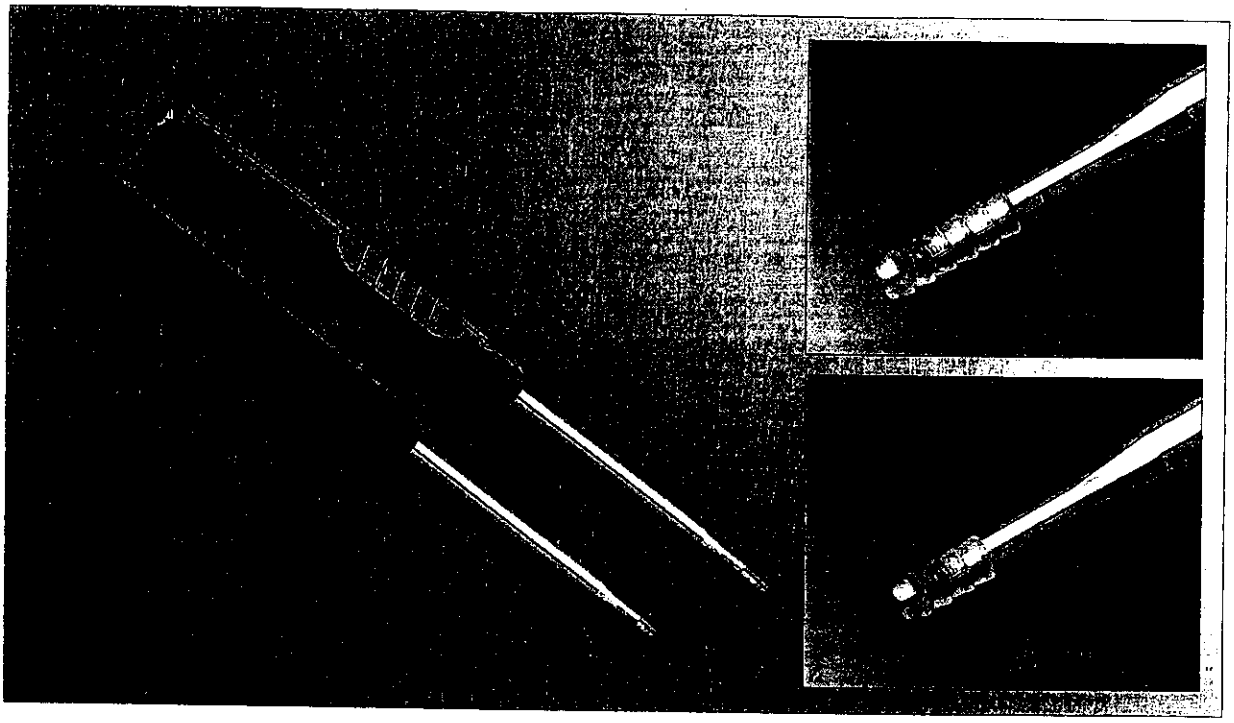
The Tenodesis Screws, used in conjunction with the Bio-Tenodesis Screw System, are available in PLLA and titanium. They are specifically designed for ligament or tendon-to-bone repairs or reconstructions utilizing both interference screw and suture anchor fixation principles. The round screw head provides protection of the graft after insertion. The Tenodesis Screw may also be used for suture fixation alone when used in conjunction with #2 or 2-0 FiberWire to facilitate intraoperative tissue shifting and tensioning. PLLA or titanium Tenodesis Screw insertion provides secure fixation for proximal and distal biceps reconstruction, collateral ligament repairs or reconstructions, ACL backup fixation and other intraarticular and extraarticular reconstructions in the shoulder, elbow, knee, foot and ankle. To maximize fixation, the graft passing sutures can be tied over the screw after insertion.

Bio-Tenodesis Disposables Kit (AR-1675DS), sterile, qty. 5, *SU:*	
includes one each of the following:	
Drill Tip Guide Pin, 2.4 mm	AR-1250L
Suture Passing Wire	AR-1255-18
#2 FiberWire, 38 inches (blue) w/Tapered Needle, 26.5 mm 1/2 circle	AR-7200
#2 TigerWire, 38 inches (white/black)	AR-7203
Bio-Tenodesis Screw System Implants, sterile, *SU:*	
Bio-Tenodesis Screw, 4 mm x 10 mm	AR-1540B
Bio-Tenodesis Screw, 4.75 mm x 15 mm	AR-1547B
Tenodesis Screw, titanium, 5.5 mm x 15 mm	AR-1350-55
Tenodesis Screw, titanium, 4.75 mm x 15 mm	AR-1350-475
Bio-Tenodesis Screw, 5.5 mm x 15 mm	AR-1555B
Bio-Tenodesis Screw, 6.25 mm x 15 mm	AR-1562B
Bio-Tenodesis Screw, 7 mm x 23 mm	AR-1570B
Bio-Tenodesis Screw, 8 mm x 23 mm	AR-1580B
Bio-Tenodesis Screw, 9 mm x 23 mm	AR-1590B
Bio-Tenodesis Screw, 7 mm x 10 mm	AR-1670B
Bio-Tenodesis Screw, 8 mm x 12 mm	AR-1680B

Designed in conjunction with Neal ElAttrache, M.D., Los Angeles, CA, and Stephen S. Burkhart, M.D., San Antonio, TX.

U.S. PATENT NO. 6,544,281

Arthrex®



Key Words: **PLDLA implant, handled inserter, small joint, FiberWire, forked distal tip, ligament and tendon repair**

The V-Tak and Mini V-Tak are bioabsorbable implants used in small joint applications for soft tissue-to-bone repairs. The V-Tak is 2.2 mm x 7 mm and the Mini V-Tak is 2.2 mm x 4.7 mm and both come on their own handled inserters. The bioabsorbable PLDLA amorphous copolymer retains its initial fixation strength throughout the tissue-healing period of 12 weeks, and undergoes a rapid degradation process without causing a local soft tissue reaction. The anchor fully degrades in approximately 16 months.

The V-Tak and Mini V-Tak, with its unique forked distal tip, were designed to capture a FiberWire suture prethrown through soft tissue. As the anchor is inserted into a predrilled hole, the suture/tissue combination is fixated in the hole rather than on the surface of the bone. This low profile, quick, easy-to-place anchor will be especially useful in soft tissue reattachment in the hand, wrist, foot and ankle.

Primary uses include UCL and RCL repair of the thumb, carpal ligament repair in the wrist and midfoot reconstructions. The use of 3-0 FiberWire is recommended.

Mini V-Tak, 2.2 mm x 4.7 mm, sterile, qty. 5, *SU*	AR-8730B
V-Tak, 2.2 mm x 7 mm, sterile, qty. 5, *SU*	AR-8735B
V-Tak Disposables Instrument Kit, sterile, qty. 5, *SU*	AR-8735DS
Mini V-Tak Disposables Instrument Kit, sterile, qty. 5, *SU*	AR-8730DS

Recommended Suture:

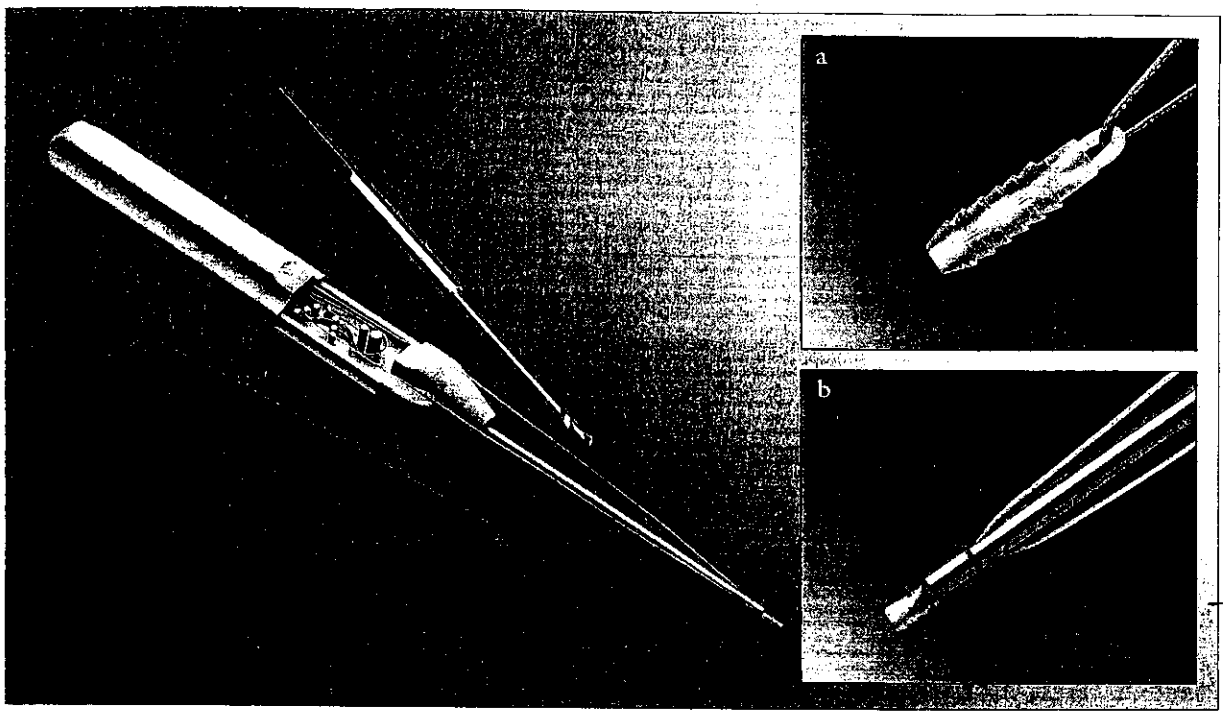
3-0 FiberWire, 18 inches (blue) w/Tapered Needle, 15 mm 3/8 circle, sterile, qty. 12, *SU*	AR-7227-01

PATENT PENDING

Actual Sizes

Arthrex®

Mini and Micro Bio-SutureTak™ w/Needles



Key Words: **PLDLA, delicate ligament and tendon repairs, hand, wrist and elbow, foot and ankle, FiberWire suture, low profile**

The Mini and Micro Bio-SutureTaks are bioabsorbable PLDLA amorphous copolymer anchors that retain their initial fixation strength throughout the tissue healing process, and then undergo a rapid degradation process. They are available loaded with 2-0 FiberWire nonabsorbable composite suture and two 17.9 mm 3/8 circle needles for delicate ligament and tendon repairs in the hand, wrist, elbow, foot and ankle.

The Mini Bio-SutureTak is a 2.4 mm outer diameter x 7 mm length anchor. This low profile, easy-to-place anchor will be especially useful in UCL repair of the thumb, scapholunate ligament repairs in the wrist, lateral ankle ligament repairs, and capsular reattachment and closure following Hallux Valgus reconstruction.

The Micro Bio-SutureTak is a 2.4 mm outer diameter x 5 mm length anchor and will be especially useful in digital collateral ligament repairs and tendon reattachments in the hand and foot.

Mini Bio-SutureTak w/Needles, 2.4 mm x 7 mm, w/handled inserter and 2-0 FiberWire, sterile, qty. 5, *SU (a)*	AR-1322BNF
Micro Bio-SutureTak w/Needles, 2.4 mm x 5 mm, w/handled inserter and 2-0 FiberWire, sterile, qty. 5, *SU (b)*	AR-1320BNF

Required Instrumentation:

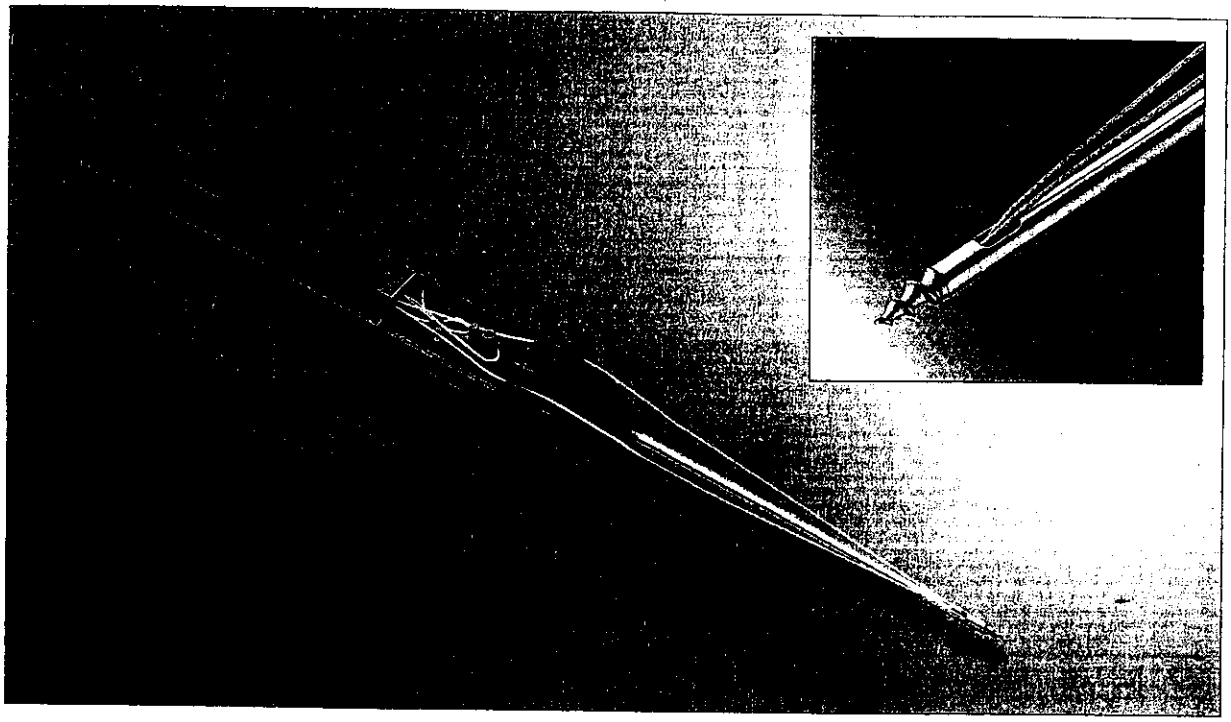
Mini Bio-SutureTak Disposable Instrument Set, *SU*	AR-1322DS
Micro Bio-SutureTak Disposable Instrument Set, *SU*	AR-1320DS

U.S. PATENT NO. 5,964,783

Actual Sizes

Arthrex®

Small Bone FASTak™ Suture Anchor



Key Words: **Soft tissue fixation, no predrilling, swedged-on needles, hand insertion, small bone, small joint**

The Small Bone FASTak is a fully threaded 2.4 mm x 7.5 mm titanium suture anchor that is preloaded with 2-0 FiberWire. It comes on a handled inserter with two 17.9 mm 3/8 circle swedged-on tapered needles.

The Small Bone FASTak is screwed directly into bone without predrilling. It is designed for use in the hand, wrist and elbow for soft tissue reattachment procedures such as UCL repair of the thumb, ligament repair for scapholunate disassociation in the wrist, as well as ECRB repair in Tennis Elbow debridement. This device can also be used to repair lateral ankle ligaments for a modified Brostrom procedure.

A recent study has shown that threaded screw-in suture anchors have significantly more fixation strength than the Nitinol arc "barbed" suture anchors. Threaded screw-in suture anchors further reduce the risk of tissue separation from the point of fixation due to anchor slip.

Small Bone FASTak Suture Anchor, 2.4 mm x 7.5 mm
w/handled inserter and 2-0 FiberWire, sterile, qty. 5, *SU* AR-1322-752SF

U.S. PATENT NO. 5,683,401 and PATENT PENDING

Actual Size

ARM 18556